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From: Rendall, Jennifer (PHAC/ASPC)
Sent: 2021-02-12 2:31 PM
To: PHAC.F EC-Members F.ASPC
Subject: Debrief - PHAC VP Min meeting February 11

Hello all,

Please find below a short debrief from the PHAC VP – Minister bilat yesterday.

The meeting agenda focused [redacted] There were additional conversations on the Vaccine Task Force (VTF) and forward planning, including booster shots, and a brief update on vaccine allocation.

The meeting began with a conversation on [redacted]

There was an extended discussion about ongoing research and forward planning in relation to vaccines and the pandemic more broadly. The Minister flagged that PSPC has been posed the question about COVID vaccine boosters. It was noted that the Vaccine Task Force would be well placed to take stock of their forward workplan over the coming year or so as the pandemic evolves. There was a general recognition that PHAC continue to explore this space as work continues on "living with COVID". It was noted that initiatives stood up in short term to address the pandemic are operationally sustainable in the long term.

The meeting concluded with a brief update on upcoming vaccine allocation discussions with PTs, with a particular focus on upcoming shipments and making temporary adjustments to ensure Q1 commitments to the territories are met.

Action items

- PHAC to follow-up with PSPC on vaccine boosters
- [redacted]
- Undertake preparatory work and forward workplanning with VTF on vaccines in coming year, including booster shots
    - Provide materials accordingly for Ministerial appearance at VTF.

Next Meeting: February 25

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From: Bent, Stephen (PHAC/ASPC)
Sent: 2020-12-07 6:59 AM
To: Elmslie, Kim (PHAC/ASPC)
Cc: Renee David; Denis, Joel (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Gobeil, Simone (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Charos, Gina (PHAC/ASPC)
Subject: Draft CDMH Materials
Attachments: DRAFT EN_VIC CDMH Deck_Dec 3 2020 v2(SB).ppt; DRAFT SPs for VIC at CDMH - Dec 3 2020 v2(SB).docx; DRAFT VIC PT opt out letter 2020-12-03 v3(SB).docx

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Hi Kim,

Here are the draft CDMH materials (thanks to SPPB for leading on these):

- Draft deck
- Draft speaking points, modelled after the ones Howard used for SAC

Also attached is the draft letter to PTs. We are working on a customized one for QC.

Thanks

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DRAFT

NO-FAULT VACCINE INJURY COMPENSATION IN CANADA

FPT Conference of Deputy Ministers of Health – December 9, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- To discuss provincial and territorial interests in a federally-funded pan-Canadian no-fault Vaccine Injury Compensation (VIC) program covering all Health Canada authorized vaccines or immunoglobulins that protect Canadians from vaccine preventable diseases.

Overview of the Presentation

- Vaccine Injury Compensation Program Drivers
- Overview of Program Elements
- Overview of Program Design
- Key Considerations
- Communications Approach
- Proposed Next Steps

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Vaccine Injury Compensation Program Drivers

Long-standing gap	• Establishing a national compensation program would leave a legacy of a strengthened immunization system in Canada. • Federal involvement in immunization activities and immunization safety through initiatives such as the National Immunization Strategy (2003).
Fairness and equity	• Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians. • Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.
Securing supply	• As the only G7 country without a national vaccine injury compensation program, Canada could be at a competitive disadvantage as manufacturers assess local market conditions before deciding where to market new vaccines. • Removes barriers to market entry for smaller manufacturers.
Leadership and responsibility	• Demonstrates that Canada, like other countries, recognizes that in the rare instances of serious harm due to vaccination, it is a right that individuals receive compensation. • Quebec is the only province with an established program since the 1980s, a model of leadership in this area.

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Overview of VIC Program Elements

A VIC Program would provide insurance in the event of a serious vaccine injury (e.g. permanent disability or death):

- Serves five key functions, including: receiving claims; validating claims; assessing claims to determine causality; recommending/rejecting compensation; paying claims.
- Allows fair compensation for all Canadians who are injured or harmed, not just those from one province.
- Awards compensation irrespective of fault or negligence or parties involved.
- Includes coverage for all vaccines approved by Health Canada.
- Expected to apply to measurable uninsured damages or costs.
- Causality, degree of disability and compensation to be determined by an appropriate expert body.

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Overview of VIC Program Design

- Funded by the Government of Canada and administered by a Third Party. If no suitable Third Party is identified, program will be administered by Public Health Agency of Canada.

- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts. Decisions to award compensation would be made by the Third Party, in accordance with the funding agreement.

- Intention is to use Quebec's VIC regime as the model for designing a pan-Canadian program to the extent possible, recognizing that it will not be feasible to duplicate every feature.

- Coverage will extend to all vaccines administered in Canadian territory **on or after [December 8th, 2020]**:
  - Ensures that compensation coverage will be in place prior to the administration of COVID-19 vaccine.
  - Formal program implementation, however, would follow by June 2021.

- P/Ts, including Quebec, will have the flexibility to opt out of the pan-Canadian program to administer an equivalent program, with federal funding provided if the program meets federal objectives.

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Key Considerations

Current lack of alignment with other G7 countries

- Risk that vaccine suppliers will favour countries that have no-fault VIC programs.

Effect on vaccine confidence

- **Little data** available to assess if the introduction of no-fault VIC program is associated with an increase or decrease in immunization coverage rates, either immediately or over the longer term (see Annex 3).
- Transparency on vaccine communications overall supports vaccine confidence.

Timing

- Introducing a VIC program before COVID-19 vaccine roll-out could fuel sentiment that government doubts the safety of vaccines.
- Delaying the program until COVID-19 vaccine roll-out is underway could similarly trigger concerns that a safety risk has been identified.

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Communications Approach

- Begin to introduce vaccine injury compensation into communications with Canadians now as part of updating them on COVID-19 vaccine roll-out plans.
  - Main message is the VIC puts Canada on an equal playing field with other countries and helps with Canada's competitiveness in accessing vaccines.

- Approach VIC communications by integrating it into overall vaccine roll-out planning information to Canadians (part of entire suite of efforts) rather than shining a light on it as a new program – correcting a gap in Canada's immunization policy.

- Liaise with FPT PHN communications table to assist with coordination of complementary messaging.

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Proposed Next Steps

- Engagement with F/P/T Health Ministers (December 2020).
- Decision required by each P/T whether to opt-out of pan-Canadian VIC and establish equivalent program (end of December 2020).
- Integrate VIC messaging and tactics into overall vaccine communications roll-out plan and develop evidence based messages designed to motivate the appropriate behaviour (underway).
- F/P/T engagement on program design and implementation (Winter 2021).
- Solicitation of interest and award of competitive process for a Third Party administrator (Spring 2021).
- Expected program launch, accepting claims for immunizations received on or after [December 8th, 2020] (June 2021).

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Annexes

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Annex 1 – Sample Key Messages

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life

- Establishing a vaccine injury compensation program is part of Canada's broader vaccine strategy and will help ensure we remain competitive in accessing new vaccines as they become available
  - We need Canada to be on an equal playing field with other countries
  - This VIC program brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from an adverse reaction to a vaccine
  - This is extremely rare – less than one in a million

- In the rare event that a Canadian were to fall ill, they should not spend their time litigating in court for a settlement – they deserve fair compensation, which this program offers

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Annex 2 – What we have learned from Quebec

- Quebec's successful no-fault VIC Program could provide the scope for a **pan-Canadian regime**.
- Since its creation by legislation, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec.

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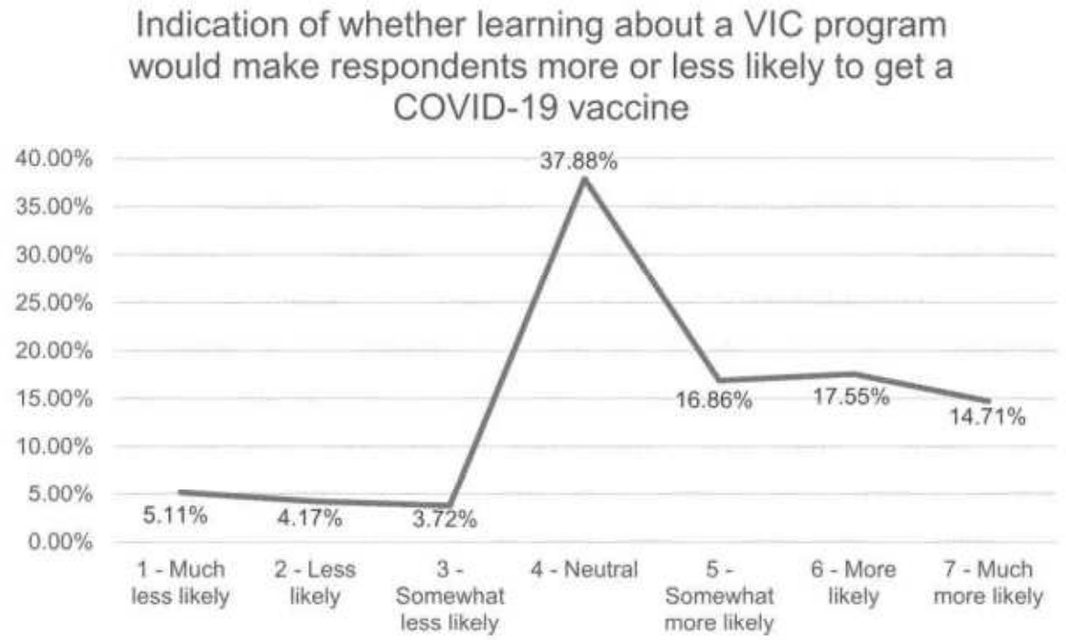
Annex 3 – Impact of VIC on Intention to Vaccinate

- Initial results from **research on the impact of learning about a national, no-fault VIC program on Canadians' intentions to be vaccinated against COVID-19*** conducted by PCO have revealed that:
  - Learning about a national VIC program **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VIC program would negatively impact their intentions to be vaccinated.



*Privy Council Office *Impact of a National, No-Fault Vaccine Injury Compensation Program on Intentions to be Vaccinated Against COVID-19: A Preliminary Analysis,* November 2, 2020. Sample size (n=1,580 Canadians).

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Meeting with FPT Canadian Deputy Ministers of Health
December 9, 2020

Speaking Points for Presenter (TBC)

CONTEXT

OBJECTIVE AND DISCUSSION FORMAT:
CDMH members will be informed of the federal government's intent to implement a pan-Canadian no-fault Vaccine Injury Compensation program in the coming months.

A deck will be presented outlining the proposed program and forward plan, and a discussion will follow.

1. No-fault Vaccine Injury Compensation in Canada

Context: Recognizing that vaccination is an area of shared jurisdiction, a deck will be presented to inform provincial and territorial stakeholders of the federal intent to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program, while also acknowledging that both timing and communication of this program may impact public perceptions pertaining to an eventual COVID-19 vaccine. Next steps will be presented and discussed including but not limited to, support for clear and aligned messaging, opt-out options and federal funding for provincial programs that meet federally-established criteria.

The federal VIC program intends to draw lessons from Quebec's established and successful VIC program for its design and implementation.

Slide 2: Purpose and overview of presentation

- Today, I want to advise the table that the Government of Canada intends to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program to cover all Health Canada-approved vaccines administered as of [December 8th, 2020]. There will be an opportunity for

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provinces or territories to opt out and administer a similar program, which I will talk about further in the presentation.

- I would also like to obtain your views and thoughts on how best to implement this program within the context of the COVID-19 vaccine roll out. The Special Advisory Committee discussed the proposed program last week and had a constructive conversation.

- Before we start our discussion, I would ask that we keep these discussions confidential for the time being. There are communications sensitivities in implementing a vaccine injury compensation program concurrent with the COVID-19 vaccine roll-out, which I will touch on a bit later in the presentation.

Slide 3: VIC program drivers

- Four key drivers are prompting this action now. There have been previous FPT discussions on VIC programming in the context of the National Immunization Strategy but it ultimately did not move forward.

- We now have an opportunity to close a long-standing gap, and implement a federal pan-Canadian program. We recognize that Quebec has provided leadership in this area, and we wish to see all Canadians enjoy the same benefits as those who are vaccinated in Quebec.

- We will be asking Canadians to roll up their sleeves for the Covid-19 vaccine and it's only fair that they have access to a

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no-fault compensation program for the rare instances where serious injury does occur.

- While the ethical principles are important, we also need to ensure that we are on a level playing field with other countries. Vaccine manufacturers are increasingly considering the presence of injury compensation programs in deciding where to seek authorization for their products.

Slide 4: Overview of VIC Program Elements

- This program would cover all vaccines approved by Health Canada. Compensation would be provided to individuals irrespective of fault, negligence, or parties involved.

- The assessment of injury causality is an essential element of the program and would be determined by an appropriate expert body.

- The only recourse currently available for Canadians outside of Quebec is to take manufacturers to court and seek damages – and to date, no court has awarded damages.

Slide 5: Overview of VIC Program Design

- The pan-Canadian program would be federally funded and administered by an arms-length Third Party. In the absence of a suitable Third Party, PHAC would be the administrator.

- We recognize that some jurisdictions may wish to administer their own program, or in the case of Quebec, continue

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administering their own program. There is some flexibility to opt-out, but we will need to move quickly, and once the contribution agreement with the administrator is in place, the window to opt-out with federal funding will close for the duration of the agreement (5 years).

- Eligibility for the program would begin on [December 8th, 2020]. Canadians would have up to 3 years to file claims consistent with Quebec's requirements.

Slide 6: Key Considerations

- Canada is currently the only G7 country without a national vaccine injury compensation program and over 2 dozen countries now have some form of a program in place. We can expect the presence of a VIC to become increasingly important to vaccine manufacturers as more countries implement VIC programs.

- I realize that vaccine confidence is a topic of significant interest, and we were seized with understanding the potential impact of introducing a VIC while planning an ambitious rollout of COVID-19 vaccines.

    - We are mindful of the potential impact of announcing a VIC and have started considering communications approaches, which I will speak to in the next slide

- Very little data is available on the effect on confidence in vaccines and immunization rates following the implementation of a no-fault VIC program in other countries. We are undertaking public opinion research to ensure that

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we understand the impacts that a program may have on the COVID-19 vaccine deployment, and are prepared to minimize any negative effects.

- Initial research results have indicated that learning about a pan-Canadian VIC program would either have no effect or a positive impact on intentions to be vaccinated against COVID-19 for a large majority of Canadians.

- We're aware that timing is a consideration on how a VIC program could be perceived by the public.

Slide 7: Communications Approach

- Given the considerations at play, we have started to develop a communications approach to manage potential communications risks.

- The planned approach would be low-key and integrated into the overall vaccine rollout communications planning.

- We have prepared some proposed key messages (in the annex), and will liaise with the FPT PHN communications table to assist with the coordination of complementary messaging.

Slide 8: Proposed Next Steps

- We will be bringing this topic forward to CDMH next week, and will engage with appropriate existing tables. We do not want to introduce an overly burdensome process when you are already very busy.

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- Provinces and territories will need to decide on their preferred course of action; that is, whether they wish to have their residents covered under the pan-Canadian VIC program being established or whether they would like to be supported with their own respective program, **by the end of December 2020**. Bilateral discussions would then ensue to discuss terms for opting out.

- As we move forward, we plan to engage with the CIC on program design and implementation, continue to update SAC, and can return to CDMH to provide updates.

Additional questions for discussion

- Does anyone have preliminary thoughts they would like to share on vaccine injury compensation?

- Any experiences in other areas that you would want us to leverage?

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

[*Correspondent's Name, Title, & Address*]
xxxxxxxxxxxxx
xxxxxxxxxxxxxx
xxxxxxxxxxxxxx

Dear [*Name of Correspondent*]:

I am pleased to inform you that that the Government of Canada is moving forward to establish a pan-Canadian no-fault vaccine injury compensation (VIC) program. This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious injury due to vaccination, it is right that individuals receive compensation. The program will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national VIC programs in place.

The parameters of the VIC program have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, and at the FPT Deputy Ministers of Health Committee on December 9, 2020.

The VIC program will provide coverage for uninsured costs resulting from life-altering, permanent injuries sustained following administration of any Health Canada-approved vaccines, including COVID-19 vaccines, on or after [December 8th, 2020], and be entirely federally funded. The expectation is that a Third Party administrator, selected through a competitive solicitation process, will manage the VIC program; however, if a suitable third party cannot be identified, the Public Health Agency of Canada will administer the program. Our goal is to have a Third Party administrator in place and able to accept claims for compensation by June 1, 2021. The initial agreement with a Third Party administrator will be for five years, with a review of the program at that time.

Recognizing that immunization is an area of shared responsibility while also ensuring that every Canadian has equal access to compensation, provinces and territories have the flexibility to opt out of the pan-Canadian VIC program should they wish to develop and implement an equivalent program within their own jurisdiction. In such cases, federal funding would be available to support the

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provincial or territorial program, provided that it meets federal objectives and criteria.

A provincial or territorial program would need to encompass certain parameters, including:

- Program to be established in 2021 with coverage as of [December 8th, 2020];
- Coverage applying to all Health Canada-approved vaccines;
- Program design to be "no-fault";
- Compensation to cover serious permanent disability;
- Applicants to have a three year window to apply for compensation; and
- Program to include an appeal mechanism for unsuccessful claimants.

Further details will be discussed in bilateral engagements, where necessary.

In order to ensure sufficient time is available for the preparatory phase of program design and implementation of the federal program, we are seeking early confirmation of whether your jurisdiction wants its residents to be covered by the pan-Canadian VIC Program or whether your jurisdiction wishes to implement a program specific to your residents.

We kindly ask that you advise us of your intention by **[December 21, 2020]**, so that we are able to proceed with the next steps of implementing the pan-Canadian VIC program, including establishing the appropriate program and funding requirements. Given the communications sensitivities in implementing this program concurrent with the COVID-19 vaccine rollout, we appreciate you keeping the program confidential until it is announced publicly.

In the meantime, should you have any questions or should you wish to discuss this further, please do not hesitate to contact Ms. Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca .

Sincerely,

Iain Stewart
President

DRAFT

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DRAFT

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From: Stewart, Iain (PHAC/ASPC)
Sent: 2020-12-07 3:55 PM
To: Njoo, Howard (PHAC/ASPC); Aung-Thin, Pamela (HC/SC); Robinson, Kerry (PHAC/ASPC); Romano, Anna (PHAC/ASPC)
Cc: Rendall, Jennifer (PHAC/ASPC)
Subject: FW: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program
Attachments: PHAC_CA_Vaccine Injury Comp_2020-12-04_1030.docx; PHAC_web_VIC_2020-12-03_1507.docx; PHAC_ML_VIC_2020-12-03_1456.docx

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May I see our provincial outreach and engagement plan?
Or is this to be done through CIC / TAC / SAC?
Do we intend to go to FPT DMHealth also HMM?

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-07 12:20 PM
To: Tam, Dr Theresa (PHAC/ASPC) ; Stewart, Iain (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; McLeod, Robyn (PHAC/ASPC) ; Macey, Jeannette (PHAC/ASPC) ; Rendall, Jennifer (PHAC/ASPC) ; Killen, Marita (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Currie, Andrea (PHAC/ASPC) ; Charbonneau, Lise (PHAC/ASPC) ; Chatigny, Elaine (PHAC/ASPC) ; Capes, Jennifer (PHAC/ASPC) ; Torunian, Michael (PHAC/ASPC) ; Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC) ; Maidment, Leanne (HC/SC) ; Magee, Heather (HC/SC) ; Allison, Catherine (HC/SC) ; HC.F Comms_Coordination F.SC ; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) ; McLachlan, Kailey (HC/SC) ; HC.F CPAB ADMO Advisors F.SC ; Earley, Jaimie (HC/SC) ; Gearey, Jennifer (HC/SC) ; Kocent, Marissa (HC/SC) ; Payette, Louise (HC/SC) ; HPOC Communications / COPS (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC ; Aylward, Brett (HC/SC) ; Nguyen, Jennifer (HC/SC) ; Ouellette, Francis (HC/SC) ; Demaine, Erika (HC/SC)
Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program
Good afternoon,
Just following up on the attached products for your approval this afternoon if possible, as we're hoping to share with MO/PCO.
Thank you!
Amanda
Amanda Ing
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-04 12:55 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC)

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<andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>
Subject: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Good afternoon,

Please see attached comms approach, media lines and web content for your approval by 5pm today, if possible.

Thank you,

Amanda

Issue: In early December 2020 (date TBD), the Public Health Agency of Canada will begin consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program. Although these discussions are meant to be held confidentially, messaging should be prepared in the event that these consultations are disclosed to media. Matters related to vaccine uptake have been dominating the media, and media coverage would be expected in this event. This messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.

Media Lines and Web Approvals:

Simone Gobeil, Mgr (2020-11-30)
Stephen Bent, DG (2020-11-30)
Jennifer Pennock, Dir SED (2020-11-30)
Celia Lourenco, HPFB (2020-12-02)
Kelly Robinson, HPFB (2020-12-02)
Megan Bettle, DG, HPFB (2020-12-02)
[redacted]
Laura Russo, Director, CPAB PCRT (2020-12-01)
Cathy Allison, DG, CPAB vaccine communications (FYI)
Dr Howard Njoo and/or Kim Elmslie (FYI)

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Pam Aung-Thin, a/ADM, CPAB (Dec 3, 2020)
HPFB ADMO (Dec 4, 2020)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
Cindy Evans, VP, EM (FYI)
DMO (FYI)
President/CPHO (pending)
MO (FYI)
PCO (FYI)
Comms Approach Approvals:
Kim Elmslie, VP IDPC (FYI)
Pam Aung-Thin, CPAB ADM (Nov 30, 2020)
EM (Nov 30, 2020)
Kaili Levesque for Patrick Tanguy, VP (Dec 4, 2020)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing
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Please note *emails to Comms_Coordination@canada.ca are monitored from 7am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*

Veuillez noter *que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Communications Approach

Vaccine Injury Compensation Program

Issue:
In early December 2020, the Public Health Agency of Canada will be consulting with provinces and territories on the establishment of a pan-Canadian no-fault vaccine injury compensation (VIC) program.

Considerations:

- Although there is significant coverage surrounding global and Canadian efforts to develop and acquire a COVID-19 vaccine, there is limited coverage and interest in the need for a vaccine injury compensation (VIC) program. Since September, the Public Health Agency of Canada has received two media calls enquiring about a VIC program in Canada.
    - *These outlets (Reuters & Global) can be leveraged in any proactive communications related to the establishment of a VIC program.*

- Implementation of a VIC program would align Canada with 26 other countries that have already implemented a vaccine injury compensation program, including all other G7 countries, thereby removing any disadvantage for negotiations with vaccine manufacturers.
    - *Communications will highlight that F/P/T governments are acting to fulfill their part of the social contract, by compensating people injured to ensure no Canadians is left behind and aligning Canadian policy with that of the global community. However, it will also need to address why Canada has not had a program until now.*

- Safety of a forthcoming COVID-19 vaccine weighs heavily on the minds of Canadians, even those who traditionally consider themselves as vaccine acceptors. Behavioural science research engaging Canadians on vaccines indicates that the majority (76%) of Canadians plan to receive the COVID-19 vaccine, but about half of this plan to delay their immunization. Establishment of a VIC now may factor into Canadians concerns about vaccine safety. However, recent behavioural science testing indicated that learning about a national VIC program **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VIC program would negatively impact their intentions to be vaccinated.
    - *Communications around a newly established VIC program will need to be transparent about the rationale for developing the program, underscore how the program puts Canada on equal footing with other governments and protects Canadians, and remind Canadians about the rarity of adverse events related to vaccination. Ongoing proactive communications related to the safety and regulatory processes in Canada prior to approval of a vaccine will also help mitigate concerns about safety.*

- Industry is expected to welcome and acknowledge the importance no-fault VIC as an appropriate measure to maintain industry investment in pandemic vaccines. The province of Quebec already has a successful no-fault VIC Program.
    - *It may be helpful to engage external experts in explaining why a VIC program is necessary (principle of reciprocity) and does not mean government is anticipating safety issues.*

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- PTs may speak publicly about vaccine compensation once the engagement process begins.
    - *It will be important to signal to Canadians that the federal government is pursuing a VIC program, in consultation with PTs, at the outset of the process.*
    - *It will also be important to emphasize and implement a coordinated communications approach, so that Canadians are receiving consistent messaging from all levels of government on VIC.*

Recommended Approach & Tactics:

A proactive communications approach is recommended that includes:

- Beginning to introduce vaccine injury compensation into communications with Canadians as part of ongoing updates on vaccine procurement and roll-out plans.
- Highlight how VIC puts Canada on an equal playing field with other countries, helps with Canada's competitiveness in accessing vaccines, and ultimately, ensures that no Canadian is left behind in the rare event of an adverse outcome.

Tactic	**Timing**	**Communications products**	**Lead**
Messaging - For PTs - For Ministers' inclusion in remarks - For media	December 1-2	Key messages Qs As	Immunization Strategic Communications
Web presence	Week of November 30	Web content	Immunization Strategic Communications and Digital Communications
Outreach to media who have enquired about VIC	Week of November 30	Media statement/update	Media Relations and Immunization Strategic Communications
Outreach to PTs, including PT Comms	Week of November 30	Share common messages and products	Immunization Strategic Communications and VRAT

Key Messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories.
- Establishing a VIC program is part of Canada's broader vaccine strategy and would help ensuring we remain competitive in accessing new vaccines as they become available.
    - We need Canada to be on an equal playing field with other countries.

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    - A VIC program would bring Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help in the rare event that someone should happen to fall ill from an adverse reaction to a vaccine.
    - This is extremely rare—less than one in a million.
- In the rare event that a Canadian were to fall ill, they should not spend their time litigation in court for a settlement—they deserve fair compensation, which this program offers.
- As the scope of this program is under discussion with the provinces and territories, no further details can be disclosed at this time.

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Media Lines –

Vaccine Injury Compensation program

Issue: In early December 2020 (date TBD), the Public Health Agency of Canada will begin consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program.

Web content is being developed to reference these consultations. Messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.

Key messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC), is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories.
- This will strengthen national immunization campaigns by ensuring equitable access/coverage to vaccines for all individuals immunized in Canada.
- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from a serious adverse reaction to a vaccine. This is extremely rare – less than one in a million
- In the very rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement – they deserve fair compensation.
- Establishing a VIC program as part of Canada's broader vaccination strategy and will help ensure that we remain competitive in accessing new vaccines as they become available, and ultimately protect Canadians.
- It also brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.
- As the scope of this program is still under discussion with the Provinces and Territories, no further details can be disclosed at this time.

If pressed on state of FPT discussions:

Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories

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are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury compensation (VIC) program

Questions and Answers:

Q1. Does the Government of Canada have confidence in the COVID-19 vaccines for which it has advance purchase agreements?

Vaccines are a critical way to limit the spread of the virus. They are effective and safe for protecting our health, as well as the health of family and community members.
Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target. The department will not authorize any drug or vaccine unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements. Health Canada continues to monitor their safety and effectiveness once they are on the market.

Q2. What is the likelihood of a possible adverse events following immunization?:

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g. muscle aches, bruising, mild headache, etc) to very rare but serious adverse events (e.g. paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and effectiveness of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Q3. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines

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quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

HC has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs in order to ensure they can be sold.

At this time, we cannot disclose details of specific agreements in an effort to protect our negotiating position and commercially sensitive pricing information, as well as to respect confidentiality clauses in our vaccine agreements.

Q4. What will a Vaccine Injury Compensation Program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories. Establishing a VIC program will strengthen Canada's broader vaccine strategy will help ensure that Canada remains competitive in accessing COVID-19 vaccines and other new vaccines as they become available, and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national VIC programming in place.

As the scope of this program is under discussion with the Provinces and Territories, no further details can be disclosed at this time.

Q5. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization and conducting any necessary testing of samples, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.

While every effort is being made in Canada to expedite COVID-19 vaccine development, safety, efficacy and quality will not be compromised. COVID-19 vaccine(s) will be subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

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Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q6. How can Canadians be sure the vaccine will be safe if we don't have the same 10-year period as with other vaccines?

The 10-year timeline that is often quoted as the time required to develop a vaccine reflects sequential steps of pre-clinical development and separate phases of clinical trials, as well as the time needed for vaccine manufacturers to fund trials and develop their manufacturing processes. Significant research and development funding is allowing vaccine developers to greatly accelerate their processes.

The use of adaptive clinical trials, which allow ongoing assessment of data and moving from one phase to the next without large gaps, allows more rapid collection of data from clinical trials.

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization and conducting any necessary testing of samples, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.

After a vaccine is granted market authorization, Health Canada and the Public Health Agency of Canada have a joint role in monitoring its safety and effectiveness, along with vaccine manufacturers and provincial/territorial public health authorities. Enhanced monitoring systems will be in place for all COVID-19 vaccines.

Q7. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases.

Addressing vaccine hesitancy is a priority for the Government of Canada. Efforts to inform and educate Canadians to help build vaccine confidence have been part of PHAC's regular business for years.

For example, from 2017 to 2019, the PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant, to debunk misinformation on vaccine safety and importance. PHAC also leads an annual seasonal flu immunization campaign targeting groups, such as seniors over 65

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who are especially vulnerable. A subsequent childhood vaccination campaign will launch early in 2021, with similar goals and objectives to the previous one. Similar communications strategies will be used when a new COVID-19 vaccine is released to ensure that Canadians have the proper information to inform their choice to receive the vaccine when available. These campaigns use different approaches to reach different segments of the public, including advertising, public education and outreach. PHAC works with many partners, including provinces and territories and professional associations to implement these strategies.

The Chief Public Health Officer, Dr. Theresa Tam is also working with chief medical officers of health from all provinces and territories through the Special Advisory Committee and together they will work with public health staff across all jurisdictions in Canada to combat misinformation and concerns around the release of a new COVID-19 vaccine.

DRAFT

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Compensation

- The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program in consultation with the provinces and territories. Establishing a VIC program is part of Canada's broader vaccination strategy and ultimately protect Canadians. It brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.-Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs

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From: Robinson, Kerry (PHAC/ASPC)
Sent: 2021-01-19 9:52 AM
To: Tam, Dr Theresa (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Stewart, Iain (PHAC/ASPC)
Cc: Romano, Anna (PHAC/ASPC); Galus, Dianne (PHAC/ASPC); Evans, Cindy (PHAC/ASPC); Fortin2, Dany (PHAC/ASPC); Levesque2, Kaili (HC/SC); Elmslie, Kim (PHAC/ASPC); Diogo, Brigitte (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC); OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC); CCMOH SECRETARIAT / CMHC (PHAC/ASPC); Auger, Julie (PHAC/ASPC)
Subject: FW: For Pres/CPHO/DCPHO: SAC Jan.19 Agenda & Materials
Attachments: 1. SAC_Coronavirus Agenda_Jan 19_Final.doc; 3. Update to SAC on the Critical Drug Reserve EN.pptx; 3b. Framework for Managing Drugs (FINAL - EN).docx; 3d. Framework Appendix B_EN.docx

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Follow Up Flag: Follow up
Flag Status: Flagged

Good morning Theresa, Howard and Iain,

Please find attached the SAC agenda for today, along with available meeting materials.

Item 2: COVID-19 Vaccine Roll out: 1) Update on logistics and distribution; 2) Jurisdictional approaches to the temporary reduction in Pfizer vaccine deliveries

- Aim: Support and inform vaccine roll-out by actively discussing logistical and operational development and their implications.

Material: Nil

Item 3: Management of drug shortages in the context of COVID-19

- Aim: Consider progress on the COVID-19 Critical Drug Reserve (CDR) from a public health perspective in the context of COVID-19 resurgence and related pressures on health systems.

Material Attached:

- *Deck: Update to SAC on the Critical Drug Reserve*
- *Framework for Managing Drugs*
- *Framework Appendix B*

Item 4: Update on Policy Options for New Border Measures/Exemptions

- Aim: Consult with PTs to inform federal policy measures under consideration to further reduce the risk of COVID-19 importation.

Material Pending: Deck: Update on Policy Options for New Border Measures/Exemptions

Item 5: Emerging Issue: Update on Vaccine Injury Support Program (VISP)

- Aim: Inform members about next steps on VISP, following their responses to participate in the program.

Material: Nil

Additional materials will follow.

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Kerry
C 613-618-0964

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PAN-CANADIAN PUBLIC HEALTH NETWORK

RÉSEAU PANCANADIEN DE SANTÉ PUBLIQUE

Special Advisory Committee Teleconference
COVID-19

AGENDA

January 19, 2021

1:30 – 3:00 pm EST

1:30 – 1:35 **1.** *5 minutes*	**Welcome and Opening Remarks** ➢ Welcome & roll call ➢ Approval of agenda	**Chair**
1:35 – 1:55 **2.** *20 minutes*	**COVID-19 Vaccine Roll-out** **Logistics and Distribution** ➢ *For discussion* • Update on logistics and distribution of Pfizer/BioNTech & Moderna vaccines • Jurisdictional approaches to the temporary reduction in Pfizer vaccine deliveries	**Krista Brodie** **Heather Deehan** **PHAC** **All**
1:55 – 2:10 **3.** *15 minutes*	**COVID-19 Critical Drug Reserve** ➢ *For discussion* • Management of drug shortages in the context of COVID-19	**Stefania Trombetti** **HC**
2:10 – 2:40 **4.** *30 minutes*	**COVID-19 Border Measures** ➢ *For discussion* • Update on Policy Options for New Border Measures/Exemptions	**Brigitte Diogo** **PHAC**
2:40 – 3:00 **5.** *10 minutes* *10 minutes*	**Emerging Issues** ➢ *For discussion* • Update on Vaccine Injury Support Program (VISP) • Forward agendas	**Stephen Bent** **PHAC** **Kerry Robinson** **SAC Secretariat**
3:00 **6.**	**Conclusion / Next Teleconference**	**Chair**

Upcoming Teleconferences: January 21, 2021

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Managing Drug Shortages during the COVID-19 Pandemic:

Update to SAC on the Critical Drug Reserve

January 19, 2021

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Context

- Increased demand for key drugs used in the treatment of COVID-19 domestically and abroad has amplified the risk of drug shortages, now and in the months ahead.
  - ➢ During the peak of the first wave of the global COVID-19 pandemic, demand for some COVID-19 critical drugs in Canada was 2-4 times normal level.
  - ➢ Canada also experienced supply disruptions from countries that manufacture drug products or supply active pharmaceutical ingredients.

There are currently 21 active Tier 3 drug shortages in Canada. Of those, 10 are for COVID-19-related critical drugs. Since March 2020, there have been a total of 44 Tier 3 shortages. By comparison, in 2019 there were approximately 10 Tier 3 shortages, in total.

- FPT collaboration in the drug shortage space has been ongoing and intensified since the pandemic started.
- FPT collaboration in Spring 2020 led to the *Framework for the Effective Management of Drug Supply in the Context of the COVID-19 Pandemic*, which set the foundation for managing drug shortages.

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FPT Framework for the Effective Management of Drug Supply in the Context of the COVID-19 Pandemic

- This Framework sets out common principles for managing the drug supply, and includes two categories of drug supply management:
  1. Facilitating access to incremental, alternative supply; and,
  2. Creating a COVID-19 Critical Drug Reserve (CDR) to bolster collective pandemic preparedness.
- Enabling foreign-labelled supply into the country to address drug shortages was key to collective efforts to help address shortages in the first phase of the pandemic.
- In preparation for this phase, the FPT ADM Drug Shortages Table worked to develop the CDR, a safety net of key drugs used in the treatment of COVID-19 symptoms.
  - ➢ It is intended to help bolster FPT pandemic preparedness by securing this inventory in Canada for worst case scenarios, in advance of broad vaccine deployment over 2021.
- To date, with the exception of Quebec and New Brunswick, most jurisdictions are planning to participate in the CDR. Some jurisdictions have requested a supply of all drugs in the CDR while others have requested a supply of some of the drugs.

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Building a COVID-19 Critical Drug Reserve

- Bilateral MOUs are advancing for jurisdictional approvals, which build upon the key elements outlined in the DM endorsed *Appendix B to the Framework.*
  - The federal government will assume up front costs to build and manage a vendor-managed distribution model.
  - Drugs accessed by PTs according to a charge-back agreement. 70% is pre-allocated with 30% held back as a safety stock accessed based on need.
  - Cost-sharing is 70% PT/ 30% federal.
  - Initial replenishment trigger is 75% of stock remaining for a particular drug.
- The CDR will initially be stocked with three months of supply, based on historical demand as defined by PT supply targets for participating jurisdictions.
  - Potential replenishments and/or top ups to an up to six month supply would be tightly managed by a collaborative FPT process.
- Best efforts have been made to minimize any disruption to the Canadian market in procurement, and this will continue to be actively monitored during implementation.
  - Bidders are required to certify their product is additional supply not already earmarked for the Canadian market.

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Building a COVID-19 Critical Drug Reserve

- The twelve drugs for the CDR were identified based on their key role in treating COVID-19 symptoms and in consultation with critical care experts and PTs:

Tranche I

- Cisatracurium (Neuromuscular blocker)
- Epinephrine (Adrenergic agonists)
- Fentanyl (Opioid analgesic)
- Norepinephrine (Adrenergic agonists)
- Propofol (Sedative)
- Rocuronium (Neuromuscular blocker)
- Salbutamol (Bronchodilator)

Tranche II

- Ceftriaxone (Antibiotic)
- Dexamethasone (Corticosteroid)
- Hydromorphone (Opioid Analgesic)
- Midazolam (Benzodiazepine Sedative)
- Vasopressin (Vasopresser)

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Next Steps

- Moving forward, collaborative work will continue to prevent and alleviate shortages related to COVID-19 treatments, including via the CDR

MOU template with PTs for signature in participating jurisdictions. Communication options being explored.

Build the reserve by continuing to stock initial 3 month PT drug supply targets, and begin drug draw downs from CDR.

Continued monitoring and collaboration.

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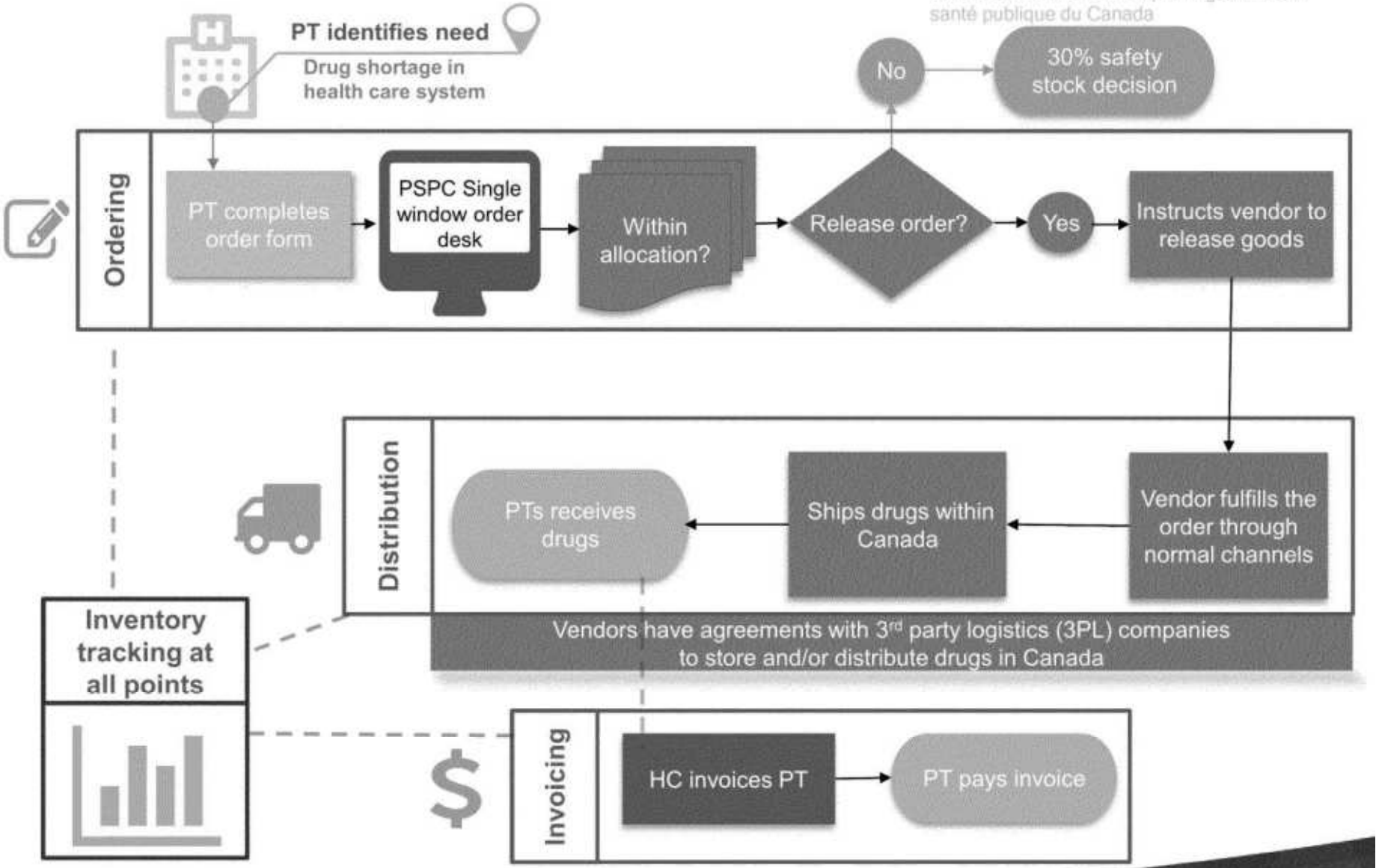
Annex A: Vendor-managed model – Distribution



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May 31, 2020

Framework for the Effective Management of Drug Supply in the Context of the COVID-19 Pandemic

Preamble

The Framework only applies to critical drug products experiencing a shortage as a result of the COVID-19 pandemic (i.e., designated Tier 3 or Anticipatory Tier 3) and will only be applied when provinces and territories have expressed their needs for these drugs over the next six months and the market is unable to meet this pan-Canadian demand.

Purpose

The purpose of this framework is to adopt:

- Common principles to manage the drug supply in the context of the COVID-19 pandemic
- An approach to managing critical drug products designated as Tier 3 or Anticipatory Tier 3 as a result of the COVID-19 pandemic for the:
    - incremental, alternative supply of drugs facilitated by the federal government (e.g., foreign-labelled drugs during a shortage)
    - reserve of federally procured drugs needed to support patients with COVID-19 and in shortage

Context

On March 11, 2020, the World Health Organization (WHO) assessed COVID-19 as a pandemic. Canada's federal, provincial and territorial governments, along with health sector partners have been working together to ensure that our preparedness and response measures are appropriate and adaptable, based on the latest science and the evolving situation.

The global pandemic has resulted in changing behaviour of Canadians (e.g., stockpiling of medication), increased demand for drug products that could be used to treat COVID-19 (including for products with limited clinical evidence to treat it) and supply disruptions from countries that manufacture drug products or supply active pharmaceutical ingredients.

Common Principles to Manage the Drug Supply

Jurisdictions agree to adopt the following principles to manage drug shortages and guide decisions in the context of the COVID-19 pandemic.

Jurisdictions will continue to leverage existing mechanisms, and work with stakeholders to identify and procure new sources of supply.

- *Solidarity*
    - Build, preserve and strengthen inter-professional, inter-institutional, inter-sectoral, and federal/provincial/territorial collaborations and partnerships

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- Shared commitment to well-being of patients
- Open lines of communication between health professionals, institutions, health sectors
- Encourage sharing of resources across health sectors and institutions
- Support each other – FPT MOU on Provision of Mutual Aid in Relation to Health Resources During an Emergency Affecting the Health of the Public

- *Fairness*
  - Fairness should be applied to decision making processes and criteria for managing/allocating drugs in shortage
  - Ensure burden not borne disproportionately by any jurisdiction
  - Maintain drug supply informed by evidence and modelling, so as not to stockpile drugs
  - Procure drugs in quantities needed to support patients with COVID-19

- *Stewardship*
  - Available resources used carefully and responsibly, using conservation measures and other best practices to preserve supply (see Appendix A)
  - Work with prescribers and other health care professionals to promote the use of drugs for their indicated uses and discourage or limit prescribing for approved medications where there is a lack of clinical evidence
  - Determine appropriate use of drug supply for clinical trials for potential Covid-19 treatments
  - Monitor drug utilization and distribution to support effective stewardship at all times

- *Openness and Transparency*
  - Allocation decisions are made using an open and transparent process with information on the rationale
  - Share information on use, anticipated demand and supply, anticipated and actual shortages trends
  - Transparency on federally-procured drugs and draw downs. Transparency on existing supplies and requirements to ensure that those with greatest need are supported
  - Decisions communicated in a timely fashion and shared with stakeholders as appropriate

- *Beneficence*
  - Highest quality care provided with resources available
  - Minimize pain and suffering
  - Appropriate use of alternative drugs or treatments where evidence suggests similar clinical efficacy
  - Communications and education about clinical effectiveness of medications for treatment of COVID-19, discouraging or limiting prescribing for medications where there is a lack of clinical evidence

- *Resource Maximization*
  - Maximize greatest possible good for the greatest possible number of Canadians

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- Share drugs within and across institutions/sectors, provinces and territories to, where possible, support unmet needs

- *FPT Collaboration*
  - Collaborative approach to manage drug supply based on above-noted principles
  - Ensure jurisdictions with greatest need during a time of drug shortage have the support of other provinces/territories

Implementing the Principles

Sustaining the current practice of facilitating access to incremental, alternative drug supply

- The federal government will continue to facilitate access to alternative supply in an effort to prevent a shortage or mitigate its impacts (e.g., US-labelled drugs)
  - Suppliers would be directed to allocate this supply based on historical demand that is further adjusted by each jurisdiction to reflect the additional needs at that point in time due to COVID-19. (e.g., surges in COVID-19 patients causing unexpected spike in demand). Allocation would not be required where the alternative supply is large enough to adequately meet the increased demand across jurisdictions.

Building a reserve of critical drugs to support patients with COVID-19

- The federal government will seek to augment supply already available to the Canadian market, through a vendor/distributor-held drug reserve
- Two tracks would be created:
  - Provinces/territories can access up to 70% based on their share of historical demand
  - The remaining percentage of the reserve can be accessed by provinces/territories based on request that demonstrates need in a transparent manner (request must be accompanied by information on current inventory, burn rate, gap quantity and timeframe)

Implementation of the Framework will be monitored and, should the need for modification arise, this will be discussed among the ADM Drug Shortages Table, as appropriate.

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Appendix A: Conservation Strategies

When there is a drug shortage, or risk of drug shortage, the following conservation and mitigation principles should be encouraged within and between jurisdictions, working as necessary with prescribers, pharmacists, professional associations and health authorities:

- To the degree possible, develop an inventory of available drugs across care settings based on available supply and criticality of need and/or demand, with ongoing reassessment;
- Review current drug prescribing practices based on available evidence of clinical efficacy;
- Reduce wastage of drugs (e.g., where evidence does not support or is weak for clinical efficacy and where it can be done safely);
- Use alternative drugs or treatments where evidence suggests similar clinical efficacy to the drug in short supply;
- Use alternative dosage forms if available and appropriate;
- Use lower dosages where evidence suggests similar clinical efficacy to the drug in short supply;
- Reassess patient medical need on an ongoing basis and adjust drug dosing or priority allocation level as appropriate; and
- Delay enrolment in research studies using drugs in short supply.

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Appendix B: Proposed Approach to Cost-Sharing

With respect to the *Framework for the Effective Management of Drug Supply in the Context of the COVID-19 Pandemic* (The Framework), the provinces and territories and the federal government have agreed that:

- The federal government will seek to augment supply already available to the Canadian market, through a vendor held drug reserve, and
- Two tracks would be created:
    - Provinces/territories can access up to 70% based on their share of demand as defined by participating jurisdictions, which would be deemed to constitute the historical demand for the purpose of the reserve.
    - The remaining percentage of the reserve can be accessed by provinces/territories based on a request that demonstrates need in a transparent manner (request must be accompanied by information on current inventory, burn rate, gap quantity and timeframe).

The purpose of this Appendix is to adopt an approach to manage the costs of acquisition, distribution and disposal of drugs held as a reserve to support jurisdictions with patients with COVID-19. It will provide the foundation upon which an FPT MOU will be developed.

Context

The global COVID-19 pandemic has resulted in increased demand for drug products that could be used to treat patients with COVID-19 and supply disruptions from countries that manufacture drug products or supply active pharmaceutical ingredients.

Health Canada is working with provinces and territories to build a reserve of critical drugs needed for the treatment of COVID-19 symptoms. The objective of the reserve is to provide a safety net for situations when the market is unable to meet pan-Canadian demand for certain drugs. The creation of a critical drug reserve will mean that drugs will be available in a timely manner should provinces/territories need them. These drugs would be purchased from global supply that is not already earmarked for the Canadian market, thus bolstering the drug supply for Canadians.

Key Elements

- A critical drug reserve is an important component in our collective pandemic preparedness. As such it is a collective responsibility that will benefit participating jurisdictions in mitigating risks of shortages.

- The volume of drugs purchased will reflect the demand of participating jurisdictions to support their needs in shortage situations.

- The federal government will make initial investments to purchase drugs to stock the reserve. Its procurement strategy will be driven by:

    - value for money - seeking multiple vendors
    - leveraging available data to inform pricing considerations
    - adjusting inventory based on the evolving situation

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- The critical drug reserve will hold a supply of drugs that are in high demand or in shortage and have all been identified by stakeholders/experts as essential in the treatment of COVID-19.

- Inventory levels will be regularly evaluated by the FPT ADM Drug Shortages Table to ensure anticipated supply will meet anticipated demand throughout the life of the reserve.

Cost-Sharing and Divestment

- Health Canada would make upfront initial investments to purchase drugs to stock the reserve. The final costs will depend on the purchase price, the number of drugs included, and the target supply for each drug.

- Costs associated with the reserve will be clearly documented and provided to the FPT ADM Drug Shortages Table on a regular basis.

- The reserve will be monitored, with regular reporting to the FPT ADM Drug Shortages Table on inventory levels and drugs drawn down from it.

- The stock in the reserve will remain current and replenishment levels will be informed by demand forecasts and FPT ADM Drug Shortages Table recommendations.

- Provinces and territories will be able to access drugs from the reserve as outlined in the Framework for the Effective Management of Drug Supply in the Context of the COVID-19 Pandemic. Upon invoicing, provinces and territories will pay 70% of the total costs, while the federal government will absorb the remaining 30% of the cost. The total cost will include the purchase price of drugs, plus inventory management and distribution (estimated at an additional 5%).

- Efforts will be made to limit and reduce the residual supply of drugs in the reserve. The cost-sharing ratio will apply to any residual drugs remaining in the reserve as of March 31, 2022. The residual drugs would be allocated to PTs, and PTs would pay 70% of the cost of the residual drugs. Allocation of the 70% share will reflect the identified demand of participating jurisdictions.

Drugs for the Reserve

- The initial list of drugs to begin supplying the reserve are noted below. These drugs were in shortage or at risk for shortage during the first wave of the pandemic, are commonly used in hospitals for treatment of critical ill patients with COVID-19, and have been recommended by critical care and other experts. The drugs are:

    - Cisatracurium
    - Rocuronium
    - Epinephrine
    - Fentanyl
    - Norepinephrine

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- Propofol
- Salbutamol

- Jurisdictions agree to recommend additional drugs for the reserve, informed by their updated supply and demand forecasts, and projected rates of COVID-19 infection. Clinical practice, including how it may evolve, will also be a consideration.

Target Supply

- A six-month supply of drugs based on demand of participating jurisdictions will be the initial target. Needs would be re-assessed every six months based on drug usage and Covid-19 case numbers. This would inform subsequent procurement of drugs, and approaches to replenishment. This represents a balance between having a meaningful supply and minimizing financial exposure.

Replenishment Strategy

- Initially, supply will be replenished once inventory of the drug falls below 75% of the six-month target supply.

- The FPT ADM Drug Shortages Table will carefully monitor the strategy to minimize residual supply and may renew and reset this trigger and other parameters respecting replenishment.

Vendor-managed Model

- A vendor-managed distribution model will be implemented, consistent with current industry practices, in an effort to minimize risk and maximize efficiencies.

- The federal government will put in place contracts for the procurement, storage, inventory rotation, and distribution of drugs through a competitive process.

- The federal government will establish an order desk for all orders from provinces and territories who will establish a single window for ordering. All orders will go through the order desk to vendors to ensure monitoring and tracking of inventory.

- Health Canada will ensure that regular reporting on inventory will be provided to the FPT ADM Drug Shortages Table.

Implementation

- To guide implementation of the cost-sharing model, MOUs will be developed for approval for all participating jurisdictions to outline key components as well as roles and responsibilities.

Effective Date

- This Appendix is in effect until March 31, 2022 or an earlier date mutually agreed to by the parties.

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From: Renee David
Sent: 2020-12-01 7:13 PM
To: Njoo, Howard (PHAC/ASPC)
Cc: Denis, Joel (PHAC/ASPC); Bent, Stephen (PHAC/ASPC)
Subject: FW: Package for briefing MO on VIC
Attachments: EN_VIC SAC Deck_Dec 1 2020.pptx; SPs for IDPCB VP on VIC Dec 1 500pm.docx; VIC critical path MINO 2020-12-01.docx

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Good evening Howard, attached are the products for the MO briefing tomorrow.

- SAC deck
- Critical path
- SPs

Please let me know if you have any comments or concerns.
Merci
Renee

Renée David
Senior Director/Directrice principale
PHAC Strategic Policy and Planning/ASPC Bureau des politiques et de la planification stratégiques
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Canada

NO-FAULT VACCINE INJURY COMPENSATION IN CANADA

Special Advisory Committee – December 3, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- To discuss provincial and territorial interests in a federally-funded pan-Canadian no-fault Vaccine Injury Compensation (VIC) program covering all Health Canada authorized vaccines or immunoglobulins that protect Canadians from vaccine preventable diseases.

Overview of the Presentation

- Vaccine Injury Compensation Program Drivers
- Overview of Program Elements
- Overview of Program Design
- Key Considerations
- Communications Approach
- Proposed Next Steps

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Vaccine Injury Compensation Program Drivers

Long-standing gap	• Establishing a national compensation program would leave a legacy of a strengthened immunization system in Canada. • Federal involvement in immunization activities and immunization safety through initiatives such as the National Immunization Strategy (2003).
Fairness and equity	• Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians. • Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.
Securing supply	• As the only G7 country without a national vaccine injury compensation program, Canada could be at a competitive disadvantage as manufacturers assess local market conditions before deciding where to market new vaccines. • Removes barriers to market entry for smaller manufacturers.
Leadership and responsibility	• Demonstrates that Canada, like other countries, recognizes that in the rare instances of serious harm due to vaccination, it is a right that individuals receive compensation. • Quebec is the only province with an established program since the 1980s, a model of leadership in this area.

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Overview of VIC Program Elements

A VIC Program would provide insurance in the event of a serious vaccine injury (e.g. permanent disability or death):

- Serves five key functions, including: receiving claims; validating claims; assessing claims to determine causality; recommending/rejecting compensation; paying claims.
- Allows fair compensation for all Canadians who are injured or harmed, not just those from one province.
- Awards compensation irrespective of fault or negligence or parties involved.
- Includes coverage for all vaccines approved by Health Canada.
- Expected to apply to measurable uninsured damages or costs.
- Causality, degree of disability and compensation to be determined by an appropriate expert body.

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Overview of VIC Program Design

- Funded by the Government of Canada and administered by a Third Party. If no suitable Third Party is identified, program will be administered by Public Health Agency of Canada.

- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts. Decisions to award compensation would be made by the Third Party, in accordance with the funding agreement.

- Intention is to use Quebec's VIC regime as the model for designing a pan-Canadian program to the extent possible, recognizing that it will not be feasible to duplicate every feature.

- Coverage will extend to all vaccines administered in Canadian territory **on or after January 1, 2021**:
  - Ensures that compensation coverage will be in place concurrently with the earliest possible date for the delivery of COVID-19 vaccine.
  - Formal program implementation, however, would follow by June 2021.

- P/Ts, including Quebec, will have the flexibility to opt out of the pan-Canadian program to administer an equivalent program, with federal funding provided if the program meets federal objectives.

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Key Considerations

Current lack of alignment with other G7 countries

- Risk that vaccine suppliers will favour countries that have no-fault VIC programs.

Effect on vaccine confidence

- **Little data** available to assess if the introduction of no-fault VIC program is associated with an increase or decrease in immunization coverage rates, either immediately or over the longer term (see Annex 3).
- Transparency on vaccine communications overall supports vaccine confidence.

Timing

- Introducing a VIC program before COVID-19 vaccine roll-out could fuel sentiment that government doubts the safety of vaccines.
- Delaying the program until COVID-19 vaccine roll-out is underway could similarly trigger concerns that a safety risk has been identified.

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Communications Approach

- Begin to introduce vaccine injury compensation into communications with Canadians now as part of updating them on COVID-19 vaccine roll-out plans.
  - Main message is the VIC puts Canada on an equal playing field with other countries and helps with Canada's competitiveness in accessing vaccines.

- Approach VIC communications by integrating it into overall vaccine roll-out planning information to Canadians (part of entire suite of efforts) rather than shining a light on it as a new program – correcting a gap in Canada's immunization policy.

- Liaise with FPT PHN communications table to assist with coordination of complementary messaging.

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Proposed Next Steps

- Engagement at key F/P/T tables, including Canadian Deputy Ministers of Health and Health Ministers (Fall 2020).
- Decision required by each P/T whether to opt-out of pan-Canadian VIC and establish equivalent program (end of December 2020).
- Integrate VIC messaging and tactics into overall vaccine communications roll-out plan and develop evidence based messages designed to motivate the appropriate behaviour (underway).
- F/P/T engagement on program design and implementation (Winter 2021).
- Solicitation of interest and award of competitive process for a Third Party administrator (Spring 2021).
- Expected program launch, accepting claims for immunizations received on or after January 1, 2021 (June 2021).

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Annexes

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Annex 1 – Sample Key Messages

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life

- Establishing a vaccine injury compensation program is part of Canada's broader vaccine strategy and will help ensure we remain competitive in accessing new vaccines as they become available
  - We need Canada to be on an equal playing field with other countries
  - This VIC program brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from an adverse reaction to a vaccine
  - This is extremely rare – less than one in a million

- In the rare event that a Canadian were to fall ill, they should not spend their time litigating in court for a settlement – they deserve fair compensation, which this program offers

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Annex 2 – What we have learned from Quebec

- Quebec's successful no-fault VIC Program could provide the scope for a **pan-Canadian regime**.
- Since its creation by legislation, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec.

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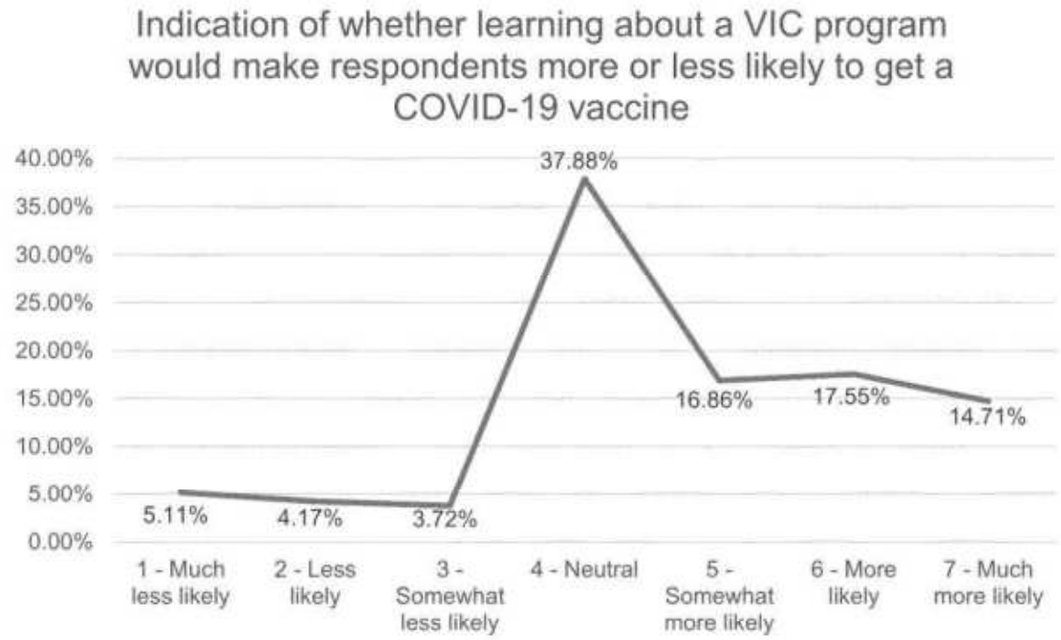
Annex 3 – Impact of VIC on Intention to Vaccinate

- Initial results from **research on the impact of learning about a national, no-fault VIC program on Canadians' intentions to be vaccinated against COVID-19*** conducted by PCO have revealed that:
  - Learning about a national VIC program **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VIC program would negatively impact their intentions to be vaccinated.



*Privy Council Office *Impact of a National, No-Fault Vaccine Injury Compensation Program on Intentions to be Vaccinated Against COVID-19: A Preliminary Analysis,* November 2, 2020. Sample size (n=1,580 Canadians).

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PHAC Update on VIC Program Implementation to the Minister's Office

December 2, 2021, 4:00pm

Speaking points for Dr. Howard Njoo

Summary:

- Before getting to next steps on VIC implementation, I want to confirm that the APA with the vaccine supplier has been finalized and signed on November 27th.
- [redacted]
- In order to progress on implementation, we need to engage with PTs as soon as possible and obtain their feedback. We recognize that they are under tremendous pressure to deliver COVID-19 vaccine rollout plans.
- We require decisions from the PTs on Program participation. We will obtain their input and identify which, in addition to Quebec, will require bilateral engagement on opting out. Presentations are:
  - December 3: SAC
  - December 9: CDMH
  - Week of December 14 (TBC): HMM
- We will need to be deliberate in our communications approach. We are mindful of the potential impact the news of a VIC would have on vaccine confidence, and the public's perception of the risks of a COVID-19 vaccine.
- Once we engage externally, there is an increased risk that news of the program could leak prematurely. Reactive media lines have been

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developed.

- Candidates for Third party administration need to be identified quickly, since there is a limited number of organizations with sufficient capacity to implement. A call for letter of interest is being prepared in order to assess viability of third party program administration as if a suitable third party cannot be identified, PHAC will administer the program.
- [redacted]
- We will continue to update your office on our progress, and engage you on each of the upcoming milestones.

Detailed version

- [redacted]
- [redacted]
- The APA with the vaccine supplier has been finalized and signed on November 27th.
- Up next, we are focussing on key milestones for **three streams of work**: 1) **FPT engagement**, 2) [redacted] and 3) identifying a **Third Party Administrator**. [redacted]

FPT Engagement:

- We plan to **approach Quebec bilaterally first**, and inform them that a federally funded pan-Canadian VIC will be presented at FPT tables this month. Their existing program will be acknowledged, and they

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will be provided with assurances that the federal government will provide funding for their program moving forward.

- Once VIC has been discussed at CDMH, the President will send a **letter to his counterparts requesting confirmation of plans to opt out of the pan-Canadian VIC**. Bilateral discussions will be scheduled with PTs as needed.

- We will need to confirm how many PTs are opting out as soon as possible, [redacted]

- The proposed date for PTs to confirm the desire to opt out is December 21.

[redacted]

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[redacted]

Third Party Administrator:

- We are developing a call for letters of interest to go out to organizations with capacity for administering such a program within our required timelines.
- Letters of Interest will be assessed and qualified organizations will be invited to submit full proposals.
- Drawing from Health Canada's experience with the Thalidomide Survivors Support Program, we do not expect a high number of applications. Health Canada received three letters of interest, and two organizations were invited to submit full proposals.
- We are developing the call now, with the intent to identify qualified organizations [redacted] If no qualified organizations come forward, PHAC will need to administer the program, [redacted]

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2020-12-01

DRAFT Critical path: Vaccine Injury Compensation Program Implementation

COVID-19 VACCINE ROLL-OUT

[redacted]

- Surveillance of vaccine safety, coverage and effectiveness (Committee Dec 8)

Milestone	Date	Deliverable
FPT Engagement		
MINO Briefing	December 2	Brief Minister's office on proposed approach with PTs prior to presenting at SAC
Engagement with Quebec (IDPCB VP)	Week of November 30	Advise Quebec of intent to implement VIC and compensate them for existing program
SAC (presenter TBC)	December 3 (TBC)	Advise of intention to establish VIC and obtain reactions
CDMH (presenter TBC)	December 9 (TBC)	
HMM (Minister Hajdu presenting)	Week of December 14 (TBC)	
Deadline to signal opt-out	Letter sent by: December 9 Deadline: December 21	Letter from PHAC President to P/T counterparts providing deadline to opt out
Opt-out discussions (if needed)	December 21-January 8 2021	Preliminary bilateral discussions to confirm scope of program and terms of funding
[redacted]		
Appointment of Third Party Administrator		
Solicit letters of interest	January 2021	Call for letters of interest sent to selected organizations with capacity to administer VIC
Contribution Agreement Signed	Week of May 3, 2021	Contribution Agreement signed by both PHAC and Third Party
Program fully implemented	**June 1, 2020**	**Applications forms are available and applicants can submit claims for compensation**

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From: Hamel, Sonia (PHAC/ASPC) on behalf of CCMOH SECRETARIAT / CMHC (PHAC/ASPC)

Sent: 2021-02-11 3:34 PM

To: Romano, Anna (PHAC/ASPC); [redacted] (Ext.); [redacted] (Ext.); [redacted] (Ext.); [redacted] (Ext.); [redacted]; Adams, Evan (SAC/ISC); Dr. George Giovinazzo; [redacted] (Ext.); Njoo, Howard (PHAC/ASPC); Dr. James Worthington; [redacted] (Ext.); [redacted] Ext.); Sharma, Supriya (HC/SC); Tam, Dr Theresa (PHAC/ASPC); Wong, Tom (SAC/ISC); Cleary, Eilish (SAC/ISC); Greg Haley; [redacted] (Ext.); [redacted] (Ext.); [redacted] SK CMOH Single Window; [redacted] Vincent Beswick-Escanlar; YK Surveillance; [redacted]

Cc: CCMOH SECRETARIAT / CMHC (PHAC/ASPC)

Subject: FYI: Launch of Call for Proposals – Pan-Canadian Vaccine Injury Support Program (VISP)

Attachments: PT VISP contact list Feb 7.docx

Dear SAC members,

As a follow-up to SAC discussion today, please find below a message from the PHAC Vaccine Injury Support Program (VISP) team.

You will also find attached the list of VISP PT contacts identified by each jurisdiction. The list will also be posted on CNPHI for ease of reference.

Thank you
SAC Secretariat

****

(Un message en Français suit)

Dear Colleagues,

As discussed at today's SAC call, the Public Health Agency of Canada (PHAC) has launched the solicitation process to identify an administrator for a no-fault support program for people in Canada with a serious and permanent vaccine injury.

Full details on the solicitation process can be found at the following link:
https://www.canada.ca/en/public-health/services/funding-opportunities/grant-contribution-funding-opportunities/call-applications-vaccine-injury-support-program.html

We would like to encourage you to please share this opportunity with your networks. The deadline for submitting an application is 11:59 p.m. PST on February 24, 2021.

Questions about the VISP, this process, or concerning the completion applications can be directed here: phac.visp-psvv.aspc@canada.ca.

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Best regards,
PHAC- VISP Team

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Chers collègues,

Tel que discuté lors de l'appel du CCS d'aujourd'hui, l'Agence de la santé publique du Canada (ASPC) a lancé un processus de sollicitation pour identifier un administrateur pour le programme de soutien sans égard à la faute pour les personnes au Canada ayant subi une blessure grave et permanente suite à un vaccin.

Vous trouverez plus d'information sur le processus de sollicitation au lien suivant: https://www.canada.ca/fr/sante-publique/services/occasions-financement/occasions-financement-moyen-subventions-contributions/appel-candidatures-programme-soutien-victimes-vaccination.html

Nous vous encourageons à partager cette opportunité avec vos réseaux. La date limite pour soumettre une candidature à l'aide du gabarit de candidature requis est le 24 février 2021 à 23 h 59 HNP.

Si vous avez des questions sur le programme, ce processus, ou sur l'application comme tel, veuillez contacter phac.visp-psvv.aspc@canada.ca.

Cordialement,
Équipe PSVV de l'ASPC

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Feb 7, 2021

List of P/T Contacts – Vaccine Injury Support Program

Jurisdiction	Contact
British Columbia	[redacted] Population and Public Health Division [redacted]@gov.bc.ca
Alberta	[redacted] Public Health and Compliance Alberta Health [redacted]@gov.ab.ca
Saskatchewan	[redacted], Ministry of Health [redacted]@health.gov.sk.ca
Manitoba	[redacted] Population Health Manitoba Health, Seniors and Active Living [redacted]@gov.mb.ca
Ontario	[redacted] Pandemic Response and Recovery Ministry of Health [redacted]@ontario.ca
Quebec	[redacted] Ministère de la Santé et des Services sociaux [redacted]@msss.gouv.qc.ca
New Brunswick	[redacted] Corporate Services and Francophone Affairs [redacted]@gnb.ca
Nova Scotia	[redacted]@novascotia.ca
Newfoundland & Labrador	[redacted] Regional Services [redacted]@gov.nl.ca
Prince Edward Island	[redacted] Health and Wellness Email: [redacted]@gov.pe.ca

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Yukon	[redacted] [redacted]Health Services Department of Health and Social Services [redacted]@gov.yk.ca
Northwest Territories	[redacted] [redacted]Policy, Legislation and Communications Department of Health and Social Services [redacted]@gov.nt.ca
Nunavut	[redacted] [redacted]Policy and Planning Department of Health [redacted]@gov.nu.ca

ATIA - 23

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From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2021-02-01 2:48 PM
To: Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Capes, Jennifer (PHAC/ASPC); Torunian, Michael (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC); Wright, Katharine (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); HC.F Comms_Coordination F.SC; Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); HC.F CPAB ADMO Advisors F.SC; Earley, Jaimie (HC/SC); Richer, Andrea (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Aylward, Brett (HC/SC); Nguyen, Jennifer (HC/SC); Ouellette, Francis (HC/SC); Filipps2, Lisa (HC/SC); Marchand, Katrina (HC/SC); Clarke, Nicola (HC/SC)
Subject: For CPHO/President Approval: ML, Web Content | Vaccine Injury Support Program
Attachments: PHAC_ML_VISP_2021-02-01_0947.docx; Invitation to Submit an application_Web Content_SPPB - 2021-02-01_0947.docx

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Good afternoon,

Please find attached web content and updated media lines for your by 9am tomorrow.

Previously approved content is highlighted in yellow. Also note, that the Solicitation web content is intended for 3rd party organizations and not intended for the general population.

Thank you,
Amanda

Context: On December 10, 2020, the Government of Canada announced that the Public Health Agency of Canada would create a Vaccine Injury Support Program (VISP). The program will provide financial support to people in the rare event that they experience a serious permanent injury after receiving a vaccine approved by Health Canada. On February 5, 2021, an open solicitation, along with targeted outreach to identified organizations will be launched to determine if there are any Canadian organizations interested and have the ability/capacity to deliver this program, while ensuring the selection is fair and transparent.

Approvals:
Patricia Salsbury, Senior Manager, Vaccine Confidence (Q- 9 - January 26)
Erin Henry, Dir, IPPD (Q9 – January 26, 2021)
Gina Charos, DG, CIRID (Q9 – January 26, 2021)
[redacted]
Stephanie Parisien, Director, SPPB (January 27, 2021)
Stephen Bent, VISP, DG (January 27, 2021)
EM and CHOPS (January 28, 2021)
Margot Geduld, Communications Executive, COVID-19 vaccine Comms (January 28, 2021)
Heather Magee, Executive Director, CPAB PCRT (January 29, 2021)

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Cathy Allison, DG, CPAB vaccine communications (January 29, 2021)
Pam Aung-Thin, a/ADM, CPAB (FYI)
Jean Tessier, A/Vice-President, Comms, PHAC (January 31, 2021)
Kim Elmslie, VP (February 1, 2021)
HPFB ADMO (FYI)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
DMO (FYI)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing
(she | elle)

Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856

Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856

***Please note** emails to Comms_Coordination@canada.ca are monitored from 8am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*

***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 8 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Call for Applications: Vaccine Injury Support Program

All vaccines used in Canada are regulated by Health Canada and must meet rigorous standards for safety, efficacy and quality before their use is authorized. Vaccinations are administered by trained professionals who follow established protocols. As a result, serious and permanent vaccine injuries are rare in Canada but, as with any medical product, they can occur.

On December 10, 2020, Prime Minister Justin Trudeau announced that the Public Health Agency of Canada will be implementing a pan-Canadian no-fault Vaccine Injury Support Program (VISP).

The VISP will ensure that people in Canada who experience a serious and permanent injury after receiving any Health Canada authorized vaccine have access to financial support. Building on the model that has been in place in Quebec for over 30 years, this pan-Canadian program will ensure fair and equitable access to support for all individuals immunized in Canada.

The Public Health Agency of Canada (PHAC) is pleased to invite eligible organizations to submit an application to administer a no-fault support program for people in Canada with a serious and permanent vaccine injury.

On this page

- Third-party administrator
- Purpose and main elements of the program
- Experience criteria
- Application process and information required
- Deadline for submission

Third-party administrator

A third-party administrator will be selected to administer the VISP via an open solicitation process. Canadian not-for-profit and for-profit organizations and corporations can apply.

The successful applicant will work independently to achieve the program's objectives, based on criteria outlined by the Public Health Agency of Canada. The Public Health Agency of Canada requires that the third-party administrator have experience and expertise in administering similar support programs. Funding to administer the program and manage financial support payments will be provided to the third-party administrator through a 5-year Contribution Agreement with the Public Health Agency of Canada.

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Purpose and main elements of the program

The purpose of the VISP is to ensure that people in Canada have access to financial support in the event that they experience a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada. Main program elements include:

Open and transparent claims intake process –a publicly accessible system for submission of injury claims that clearly outlines the process and eligibility criteria for applicants

Causality assessment –a process that objectively determines a probable causal relationship between injury and vaccine and the degree and duration of disability for the purposes of establishing payments

Administration of financial support payments to beneficiaries –financial support payments to beneficiaries based on a compensation schedule that aligns with accepted industry practices for injury compensation, and is consistent with other public and private sector compensation regimes. Financial support will include income replacement; death benefits; reimbursement of eligible costs such as otherwise uncovered medical expenses; and, injury indemnities.

Appeals process – a process by which applicants can appeal decisions made by the third party, with regards to causality and financial support.

Experience Criteria

The organization must demonstrate how it meets each of the following experience criteria:

- health claim adjudication (including an appeal mechanism);
- experience in injury causality assessments;
- cost-effective delivery in administering payments;
- managing personal information; and,
- providing program delivery at a national level in both official languages.

Application process and information required

The Public Health Agency of Canada's Vaccine Injury Support Program Application Template must be used to submit a funding application. To obtain a copy of the Application Template, please contact: phac.visp-psvv.aspc@canada.ca with the subject line "Application Template - Vaccine Injury Support Program".

Using the template, applicants will be required to provide the following:

- outline of how the organization is able to undertake the proposed program;

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- description of the organization's management structure, governance and financial capacity to carry out the program;
- demonstration of how the organization meets each of the experience criteria;
- detailed information regarding how the organization is able to undertake each of the program elements; and
- detailed information regarding expenses, resources and processes required for the program.

Further guidelines will be included within the template for the application submission.

Applications will undergo a review process. The successful applicant will be awarded funding to administer the VISP.

It is anticipated that a 5-year Contribution Agreement will be signed with the successful applicant. This 5-year period will begin on the date that the agreement is signed by both parties. The initial agreement will end five years after signing but may be extended or renewed, as appropriate.

Applicants with ineligible, incomplete or unsuccessful applications will be notified.

Deadline for submission

The deadline for submitting an Application is 11:59 p.m. PST on February 28, 2021. Complete applications must be submitted to phac.visp-psvv.aspc@canada.ca.

Please note, the Public Health Agency of Canada is under no obligation to enter into a funding agreement as a result of this invitation to submit an application. The Public Health Agency of Canada also reserves the right to reject or accept any submission in whole or in part, as well as cancel and/or re-issue this invitation to submit an application at any time. In addition, the Public Health Agency of Canada will not reimburse costs incurred in the preparation and/or submission of an application.

Application will be acknowledged by email within two business days, so please ensure your email address is included. The Public Health Agency of Canada will update you by email on the status of your submission within 10 business days following the due date of applications.

To obtain additional information about this funding opportunity, please contact phac.visp-psvv.aspc@canada.ca.

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Media Lines

Vaccine Injury Support Program

Issue: In early December 2020, the Public Health Agency of Canada (PHAC) announced that it would establish a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with provinces and territories. To identify a third party administrator for this program, PHAC is launching a solicitation process on February 5, that will run until February 28, 2021.

Previously approved content is highlighted.

Upon Announcement – Key messages:

- As Canadians, we pride ourselves on our commitment to each other. By vaccinating, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories.
- Building on the model in place in Québec for more than 30 years, this will strengthen national immunization campaigns by ensuring fair and equitable access to support all individuals vaccinated in Canada.
- All immunization programs are based on the principle of reciprocity. As such, the Government of Canada is committed to ensuring that Canadians who support public health by being vaccinated are supported should they experience a serious permanent injury as a result of vaccination. This is extremely rare—less than one in a million.
- In the rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement—they deserve fair compensation.
- It also brings Canada in line with its G7 counterparts who all provide vaccine injury support for a minimum of mandatory vaccines, with most covering all recommended vaccines for vaccine preventable diseases.
- A third party is being sought to administer the program, and an open solicitation process is now underway.

If pressed on state of FPT discussions:
Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury support program (VISP), noting that Québec has had a vaccine injury support program since 1988, and will continue to administer its program provincially.

If pressed on timing:
The establishment of a vaccine injury support program has been previously identified as an area of importance by the Government of Canada, the provinces and the territories, to ensure that Canadians who support public health by being vaccinated are supported in the rare event they are injured.

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Questions and Answers:

Q1. What will a vaccine injury support program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories. Establishing a VISP will strengthen Canada's broader vaccine strategy and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national vaccine injury support programming in place.

The VISP will ensure that people in Canada who experience a serious permanent injury after receiving any Health Canada authorized vaccine have access to financial support. A suitable Third Party will administer the VISP; if no suitable third party is identified, the program would be federally run and administered by PHAC.

More details on the program and its administration will be available in the coming months.

Q2. Why is the Government of Canada considering using a third party to run the program?

The Government of Canada is seeking to select an experienced third party to administer the program through a contribution agreement. The suitable third party administrator will be able to apply its expertise in administering similar programs that require health claim adjudication and managing personal information as well as delivering a national program in both official languages. The third party will be able to quickly implement and deliver the program in a cost-effective manner.

Q3. Who will this solicitation be open to?

The solicitation is open to Canadian for-profit and not-for-profit organizations and corporations.

Q3. Does the Government of Canada continue to monitor a vaccine's safety after it is authorized?

Canada has a robust and well-established vaccine safety surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Vaccine manufacturers are required to continue to collect information about the long-term safety and effectiveness of their products. Pfizer BioNTech and Moderna, for example, will be following

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clinical trial participants for at least two years after receiving the second dose of the vaccine. Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

Q4. What if an adverse event following immunization is reported?

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g., muscle aches, bruising, mild headache) to very rare but serious adverse events (e.g., paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and efficacy of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

AEFI reports sent to PHAC from FPT jurisdictions are collated into the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Reports of serious adverse events are submitted to PHAC within 7 days of the receipt by the jurisdiction. FPT jurisdictions also notify PHAC of any reports of deaths within 24 hrs of becoming aware of the event. Reports of serious adverse events are processed within 1-2 days of submission and undergo medical case review within 1-3 days of data processing completion. If AEFI counts/rates exceed established background rates/thresholds based on international standards and what was observed during the clinical trials, a safety signal will be issued resulting in various actions. This could include Health Canada and the Public Health Agency of Canada warning Canadians about potential side effects, Health Canada suspending a lot or changing the recommended use of the product, or removing the product from the market.

Commented [KM1]: APPROVED CONTENT on January 7, 2021 via AEFI package

Q5. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

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The Government is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Canada has a robust and well-established vaccine surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

Health Canada will continue to review all the available safety data from ongoing clinical studies and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information.

Q6. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs to ensure they can be sold.

Q7. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing all COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available.

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COVID-19 vaccine(s) are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q8. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases (VPD). Vaccine hesitancy can be attributed to factors related to confidence in vaccines (e.g. safety concerns), complacency (low perceived risk of VPDs), and convenience (difficulty accessing vaccines). The use of social media as an effective tool to spread misinformation and fear about vaccines also plays an important role in vaccine hesitancy.

Addressing vaccine hesitancy is a longstanding priority for the Public Health Agency of Canada (PHAC) but with the arrival of COVID-19, the stakes are higher than in the recent past. Concerted effort is underway with a range of partners to enhance education and guidance, address knowledge and research gaps, and improve coverage data. We are working with healthcare providers to meet the needs of frontline vaccinators and other health professionals who require tools to discuss vaccines with their patients and clients. We are also spearheading a national dialogue to meaningfully engage Canadians on about the importance of COVID-19 vaccines and vaccination more broadly.

This work builds on previous and existing efforts to improve vaccine coverage rates. For example, from 2017 to 2019, PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant as well as to debunk misinformation on vaccine safety and importance. A subsequent childhood vaccination campaign was launched (early 2021), with similar goals and objectives as well as serving as a reminder to parents to ensure children continue to stay up to date on their vaccination schedule. PHAC also leads an annual seasonal influenza immunization campaign targeting groups, such as seniors over 65 who are especially vulnerable.

PHAC is working with many partners to better understand and address vaccine hesitancy related to the new COVID-19 vaccines. These include both internal and external working groups with experts in vaccine hesitancy from different fields of study. This also includes a Vaccine Confidence Task Group made up of multidisciplinary advisors to help develop and provide the tools needed to meaningfully address vaccination questions and concerns. It also involves funding for stakeholders, provinces, territories, and community groups to help them develop tailored approaches that meet their community needs and speak in their community voices. Funding through the Immunization Partnership Fund will be leveraged to ensure Canada's diverse and often underserved groups are taking full advantage of the vaccines available to them.

Commented [KM2]: Program DG approved

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From: Auger, Julie (PHAC/ASPC) on behalf of CCMOH SECRETARIAT / CMHC (PHAC/ASPC)

Sent: 2021-01-24 1:27 PM

To: Romano, Anna (PHAC/ASPC); [redacted] (Ext.); Njoo, Howard (PHAC/ASPC); [redacted] (Ext.); Sharma, Supriya (HC/SC); Tam, Dr Theresa (PHAC/ASPC); Wong, Tom (SAC/ISC); Cleary, Eilish (SAC/ISC); [redacted] SK CMOH Single Window; [redacted] Vincent Beswick-Escanlar; YK Surveillance; [redacted]

Cc: [redacted] Auger, Julie (PHAC/ASPC); [redacted] Barton, Kimby (PHAC/ASPC); Bent, Stephen (PHAC/ASPC); [redacted] Carter, Luke (HC/SC); CCMOH SECRETARIAT / CMHC (PHAC/ASPC); Charos, Gina (PHAC/ASPC); Cindy Kruger; [redacted] (Ext.); [redacted] (Ext.); David, Renee (PHAC/ASPC); Davies, Stephanie (PHAC/ASPC); [redacted] (Ext.); Denis, Joel (PHAC/ASPC); [redacted] Elaine Barrett-Cramer; [redacted] (Ext.); Elmslie, Kim (PHAC/ASPC); Arnold, Eric (PHAC/ASPC); Evans, Cindy (PHAC/ASPC); Everitt, Louisa (PHAC/ASPC); Fournier, Sarah (PHAC/ASPC); [redacted] Guenette, Tara-Lynn (PHAC/ASPC); Hamel, Sonia (PHAC/ASPC); [redacted] Henry, Erin (PHAC/ASPC); Hill, Allison (HC/SC); Hostrawser, Bonnie (PHAC/ASPC); HPOC PHM / COPS MSP (PHAC/ASPC); Ingraham, Erin (HC/SC); [redacted] Cadorette, Katie (HC/SC); [redacted] (Ext.); King2, Arlene (PHAC/ASPC); [redacted] Hunter, Laurie (PHAC/ASPC); Lebans, Anne (PHAC/ASPC); Lewis, Darlene (SAC/ISC); Lior, Lee (PHAC/ASPC); [redacted] (Ext.); MacDonald2, Tammy (PHAC/ASPC); MacKenzie, Sara (HC/SC); Maureen Carew; [redacted] McCarney, Jane (PHAC/ASPC); McDonald, Alexa (PHAC/ASPC); McGarr, Holly (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); McNeill, Robin (PHAC/ASPC); Conly, Meghan (HC/SC); [redacted] Ext.); Mitra, Debjani (PHAC/ASPC); NB Secretariat ; Paddle, Lisa (PHAC/ASPC); Huber, Pamela (PHAC/ASPC); [redacted] Ponic, Pamela (PHAC/ASPC); [redacted] Robinson, Kerry (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Russo, Laura (HC/SC); Rutledge-Taylor, Katie (PHAC/ASPC); Salvadori, Marina (PHAC/ASPC); [redacted] Ext.); Siu, Winnie (PHAC/ASPC); Smith, Cheryl (HC/SC); [redacted] (Ext.); [redacted] Cidsc Secretariat (PHAC/ASPC); Taylor, Dorcas (PHAC/ASPC); [redacted]

Subject: For reference: Communication products on AEFIs and infection post-immunization

Attachments: PHAC_ML_Testing positive after vaccination_Jan21_FINAL_EN.docx; PHAC_KM_Bells Palsy AEFI_2021-01-21_2054_FINAL BIL.docx;

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PHAC_MLQA_Vaccine Safety_AEFI_2021_01_07_FINAL FR.docx;
PHAC_MLQA_Vaccine Safety_AEFI_2021_01_07_FINAL EN.docx

Dear SAC members,

Please find attached for your reference the following media lines/key messages:

- AEFI (EN & FR)
- Bells Palsy (EN)
- Testing positive after immunization (EN, FR to follow)

Additional communication products will be shared as they become available.

In addition, the COVID-19 Vaccination in Canada Report has now been posted based on available data. The web report provides daily updates on the total number of vaccines administered as of 11:00AM, as well as weekly updates on vaccines distributed and vaccination coverage every Friday.

https://health-infobase.canada.ca/covid-19/vaccination-coverage/
https://sante-infobase.canada.ca/covid-19/couverture-vaccinale/

Weekly updates on AEFIs can also be found here:

https://infobase-dev.com/covid/vaccine-safety/index-en.html
https://infobase-dev.com/covid/vaccine-safety/index-fr.html

Regards,
SAC Secretariat

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Key Messages

Bell's Palsy and AEFI's (Adverse Events Following Immunization)

Issue Statement: The issue of people developing Bell's Palsy—an unexplained episode of facial muscle weakness or paralysis— after getting certain vaccinations has been more prevalent in the media. Media calls are expected, so back-pocket messages have been developed to be included in the AEFI MLQ&A package.

Key Messages:

- The rates of Bell's Palsy, or facial paralysis, reported in the clinical trials for both the Pfizer-BioNTech and Moderna vaccines were no higher than those observed in the general population.
- Health Canada and the Public Heath Agency of Canada (PHAC) continue to monitor for Bell's Palsy through post-market surveillance, which also involves vaccine manufacturers and provinces and territories.
- While there have been reports of Bell's Palsy following COVID-19 vaccination, an assessment of causality has not yet been established.
- NACI (National Advisory Committee on Immunization) is monitoring the evidence and will adjust recommendations on use of the vaccine as needed.

Principaux messages

- Le taux de cas de paralysie de Bell (paralysie faciale) signalés dans les essais cliniques des fabricants de vaccins Pfizer-BioNTech et Moderna n'est pas plus élevé que celui observé dans la population générale.
- Santé Canada et l'Agence de la santé publique du Canada (ASPC) continue de surveiller les cas de paralysie de Bell par son mécanisme de surveillance post-commercialisation, qui mobilise également les fabricants de vaccins ainsi que les provinces et les territoires.
- Des cas de paralysie de Bell ont été signalés à la suite de l'administration d'un vaccin contre la COVID-19, toutefois, aucun lien de causalité n'a encore été établi.
- Le CCNI (Comité consultatif national de l'immunisation) surveille les preuves et, au besoin, modifiera les recommandations relatives à la vaccination.

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Media Lines

Adverse Events Following Immunization web updates

Issue Statement: COVID-19 vaccination began in provinces and territories the week of December 13, 2020. Transparent communications around how many people have been vaccinated against COVID-19, and how many people have reported adverse events is essential in building public trust and increasing vaccine acceptance among Canadians. Starting on January 8, Health Canada and the Public Health Agency of Canada will begin publishing a weekly web update on reported adverse events following immunization.

Key Messages:

- As of December 23, 2020, Health Canada has authorized two COVID-19 vaccines for use in Canada, one manufactured by Pfizer-BioNTech and one by Moderna.
- Health Canada authorized both vaccines after an independent and thorough scientific review for safety, efficacy and quality.
- Like any medication, vaccines can cause side effects and reactions also known as adverse events.
- Some adverse events are identified during the clinical trial process; however, new issues can arise once a health product is on the market because it is being used in a much larger number of people.
- Adverse events could be as mild as soreness at the site of injection or a slight fever, or more serious in nature, such as an allergic reaction. Such events are to be expected, and will not necessarily change the approval of a vaccine.
- Canada has a strong vaccine safety monitoring system in place that proactively engages healthcare professionals, vaccine manufacturers, the provinces and territories, the Public Health Agency of Canada (PHAC), and Health Canada.
- The Government of Canada is committed to sharing timely, accessible, and factual information to help Canadians make informed decisions about vaccination.
- As part of the Government's continued commitment to openness and transparency, Health Canada and PHAC will provide Canadians with weekly updates on reported adverse events following immunization (AEFI) on Canada.ca.
- These weekly web updates will provide information about the AEFI reports submitted to PHAC's Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) and to Health Canada's Canada Vigilance database.
- To date, Health Canada and PHAC have received some reports of events following the administration of an authorized COVID-19 vaccine in Canada, none of which are unexpected or indicate a vaccine safety concern. Details can be found here: https://health-infobase.canada.ca/covid-19/vaccine-safety/

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Questions and Answers:

Q1. What is an adverse event following immunization (AEFI)?

An adverse event following immunization (AEFI) is a medical occurrence that happens after someone receives a vaccine, which may be caused by the vaccine. The adverse event may be any:

- unfavourable or unintended sign, symptom or disease; or
- abnormal laboratory finding ((e.g., a culture result of cellulitis (bacterial skin infection) at the injection site))

Q2. What is a serious adverse event following immunization (AEFI) or an adverse event of special interest (AESI)?

An adverse event is considered serious if it:

- results in death;
- is life-threatening;
- requires in-patient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity; or
- results in a congenital anomaly/birth defect.

An adverse event of special interest (serious or non-serious) is a scientific and medical concern specific to a manufacturer's vaccine that requires ongoing monitoring and rapid communication. Vaccine manufacturers and Health Canada are monitoring COVID vaccines for AESIs.

Q3. Where can we find information on how many people have experienced adverse effects following immunization?

Canada has a strong post-market safety surveillance system in place to detect rare adverse events that may occur after vaccines are authorized. Starting in January 2021, Health Canada and PHAC will publish weekly web reports sharing data from the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) from PHAC and HC's Canada Vigilance database. This report will provide Canadians with transparent information on adverse events following COVID-19 vaccination. Data will be organized by demographics, vaccine name, reason for seriousness and type of adverse events.

Safety data from clinical trials for the authorized COVID-19 vaccines showed mostly mild or moderate adverse events, similar to other vaccines, including pain at the injection site, tiredness and muscle aches. As more people in Canada are vaccinated, other adverse events may be reported that were not detected during clinical trials given the size of the population. If any safety issues are confirmed, Health Canada will not hesitate to take appropriate action.

Q4. Will PHAC be reporting on the percentage of people who have received specific vaccines, once more vaccines become authorized for use in Canada?

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Yes, PHAC will receive and report on provincial and territorial data for vaccination coverage of specific vaccines, once more vaccines are authorized for use in Canada. A link to this information will also be available on the AEFI reports page.

Q5. Will PHAC be reporting the provincial and territorial breakdowns of adverse events?

PHAC will publish weekly reports organized by demographics, vaccine name, reason for seriousness and type of adverse events, but will not disclose a breakdown by jurisdiction. This approach will ensure transparency to Canadians, while respecting privacy considerations.

Q6. Why is it important to report an adverse event following immunization (AEFI)?

Reporting an AEFI provides vital information that is needed to identify and assess vaccine safety issues that may pose a risk to public health. This information is used, along with other vaccine safety information, to determine whether action is needed to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or removing the product from the market.

Individuals who experience an adverse event following immunization should report it to a healthcare professional. Healthcare professionals should complete the Adverse Events Following Immunization (AEFI) Form appropriate to their province or territory and send it to their local Health Unit.

Q7. What if an adverse event following immunization is reported?

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g. muscle aches, bruising, mild headache, etc) to very rare but serious adverse events (e.g. paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and efficacy of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.
Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

AEFI reports sent to PHAC from FPT jurisdictions are collated into the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Reports of serious adverse events are submitted to PHAC within 7 days of the receipt by the jurisdiction. FPT jurisdictions also notify PHAC of any reports of deaths within 24 hrs of becoming aware of the

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event. Reports of serious adverse events are processed within 1-2 days of submission and undergo medical case review within 1-3 days of data processing completion. If AEFI counts/rates exceed established background rates/thresholds based on international standards, a safety signal will be issued resulting in various actions. This could include warning Canadians about potential side effects, changing the recommended use of the product, or removing the product from the market.

Q8. What will a vaccine injury support program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories. Establishing a VISP will strengthen Canada's broader vaccine strategy will help ensure that Canada remains competitive in accessing new vaccines as they become available, and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national vaccine injury support programming in place.

As the scope of this program is under discussion with the Provinces and Territories, no further details can be disclosed at this time.

Q9. Does the Government of Canada continue to monitor a vaccine's safety after it is authorized?

Canada has a robust and well-established vaccine safety surveillance system. Once a vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Vaccine manufacturers are expected to continue to collect information about the long-term safety and effectiveness of their products. Pfizer and BioNTech, for example, will be following clinical trial participants for at least two years after receiving the second dose of the vaccine. Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

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Media Lines

Adverse Events Following Immunization web updates

Issue Statement: COVID-19 vaccination began in provinces and territories the week of December 13, 2020. Transparent communications around how many people have been vaccinated against COVID-19, and how many people have reported adverse events is essential in building public trust and increasing vaccine acceptance among Canadians. Starting on January 8, Health Canada and the Public Health Agency of Canada will begin publishing a weekly web update on reported adverse events following immunization.

Principaux messages

- En date du 23 décembre 2020, Santé Canada a autorisé l'utilisation de deux vaccins contre la COVID-19 au Canada, l'un fabriqué par Pfizer-BioNTech et l'autre, par Moderna.

- Santé Canada a homologué les deux vaccins après un examen scientifique complet et indépendant de leur innocuité, de leur efficacité et de leur qualité.

- Comme tous les médicaments, les vaccins peuvent entraîner des effets secondaires et des réactions, aussi appelés événements indésirables.

- Certains événements indésirables sont décelés pendant le processus d'essais cliniques, mais de nouveaux problèmes peuvent apparaître une fois qu'un produit de santé est offert sur le marché parce qu'il est utilisé par un bien plus grand nombre de personnes.

- Les événements indésirables peuvent être aussi bénins qu'une douleur à l'endroit de l'injection ou une faible fièvre, ou de nature beaucoup plus grave (p. ex. réaction allergique). Il faut s'attendre à ce que des événements indésirables se produisent, et cela n'entraînera pas nécessairement de changements à l'homologation d'un vaccin.

- Le Canada a en place un robuste système de surveillance de l'innocuité des vaccins qui mobilise de manière proactive les professionnels de la santé, les fabricants de vaccins, les provinces, les territoires, l'Agence de la santé publique du Canada (ASPC) et Santé Canada.

- Le gouvernement du Canada est déterminé à communiquer rapidement des renseignements accessibles et factuels pour aider les membres de la population canadienne à prendre des décisions éclairées à propos de la vaccination.

- Dans le contexte de l'engagement continu du gouvernement du Canada en matière d'ouverture et de transparence, Santé Canada et l'ASPC fourniront à la population canadienne des mises à jour hebdomadaires au sujet des événements indésirables associés aux vaccins (EIAV), aussi appelés effets secondaires suivant l'immunisation (ESSI), sur Canada.ca.

- Ces mises à jour hebdomadaires sur le Web présenteront de l'information concernant les déclarations d'EIAV transmises au Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) et à la base de données Canada Vigilance de Santé Canada.

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- À ce jour, Santé Canada et l'ASPC ont reçu des signalements d'événements indésirables suivant l'administration d'un des vaccins contre la COVID-19 homologués au Canada; du nombre, il n'y a pas d'événements indésirables inattendus ou qui suscitent des préoccupations par rapport à l'innocuité des vaccins. Les détails sont affichés ici : https://sante-infobase.canada.ca/covid-19/securite-vaccins/

Questions et réponses

Q1. Qu'est-ce qu'un événement indésirable associé aux vaccins (EIAV)?

Un événement indésirable associé aux vaccins (EIAV), aussi appelé effet secondaire suivant l'immunisation (ESSI), est un fait médical qui se produit après qu'une personne ait reçu un vaccin et qui peut être causé par ce vaccin. Est considéré comme un événement indésirable tout cas de l'une ou l'autre de ces situations :

- maladie, symptôme ou signe défavorable ou non intentionnel;
- résultat de laboratoire anormal (notamment le résultat d'une culture indiquant une cellulite [infection de peau] au site d'injection).

Q2. Qu'est-ce qu'un événement indésirable associé aux vaccins (EIAV) grave ou un événement indésirable d'intérêt particulier (EIIP)?

Un événement indésirable est considéré comme grave dans n'importe laquelle de ces circonstances :

- s'il entraîne la mort;
- s'il met la vie en danger;
- s'il exige l'hospitalisation du patient ou la prolongation d'une hospitalisation en cours;
- s'il entraîne une incapacité ou un handicap persistent ou important;
- s'il entraîne une anomalie congénitale.

Un événement indésirable d'intérêt particulier (grave ou non) est une préoccupation d'ordre scientifique et médical propre au vaccin d'un fabricant qui exige un suivi permanent et une communication rapide. Les fabricants de vaccins et Santé Canada font le suivi des événements indésirables d'intérêt particulier associés aux vaccins contre la COVID-19.

Q3. Où pouvons-nous trouver de l'information sur le nombre de personnes chez qui des événements indésirables associés aux vaccins (EIAV) sont survenus?

Le Canada a en place un robuste système de surveillance de l'innocuité des vaccins après leur mise sur le marché pour la détection d'événements indésirables rares pouvant se produire après l'homologation de vaccins. À compter de janvier 2021, Santé Canada et l'ASPC fourniront à la population canadienne des rapports hebdomadaires sur le Web au sujet des données tirées du Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) de la base de données Canada Vigilance de Santé Canada. Ces rapports fourniront à la population canadienne de l'information transparente à propos des événements indésirables survenus après l'administration de vaccins contre la COVID-19. Les données seront regroupées

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en fonction de caractéristiques démographiques, du nom du vaccin en cause, de la raison de la gravité des événements indésirables et du type d'événement indésirable.

Les données d'innocuité tirées des essais cliniques menés avec les vaccins contre la COVID-19 homologués montrent que les événements indésirables survenus (p. ex. douleur au site d'injection, fatigue, courbatures) étaient surtout bénins ou modérément graves, comme c'est le cas pour les autres vaccins. En raison de la taille de la population, il se pourrait que des événements indésirables qui n'ont pas été relevés au cours des essais cliniques soient signalés au fur et à mesure que le nombre de personnes vaccinées au Canada augmentera. Dans l'éventualité où des problèmes liés à l'innocuité sont confirmés, Santé Canada n'hésitera pas à prendre les mesures qui s'imposent.

Q4. L'ASPC fera-t-elle rapport sur le pourcentage de personnes ayant reçu chaque vaccin une fois que l'utilisation d'un plus grand nombre de vaccins aura été autorisée au Canada?

Oui, l'Agence de la santé publique du Canada (ASPC) recevra les données des provinces et des territoires concernant la couverture vaccinale de chaque vaccin, une fois que l'utilisation d'un plus grand nombre de vaccins aura été autorisée au Canada, et fera rapport à ce sujet. Un lien vers ces renseignements sera affiché sur la page des rapports sur les événements indésirables associés aux vaccins (EIAV).

Q5. L'ASPC publiera-t-elle la ventilation provinciale et territoriale des événements indésirables?

L'ASPC diffusera des rapports hebdomadaires dont les données seront regroupées en fonction de caractéristiques démographiques, du nom du vaccin en cause, de la raison de la gravité des événements indésirables et du type d'événement indésirable, mais ne divulguera pas la ventilation par administration. Cette approche garantira la transparence à l'égard de la population canadienne dans le respect des considérations relatives à la protection de la confidentialité.

Q6. Pourquoi est-ce important de déclarer un événement indésirable associé à un vaccin (EIAV)?

La déclaration d'un événement indésirable associé à un vaccin (EIAV) fournit de l'information cruciale requise pour déceler et évaluer les problèmes concernant l'innocuité des vaccins qui peuvent constituer un risque pour la santé publique. Cette information est utilisée de concert avec d'autres renseignements relatifs à l'innocuité des vaccins pour déterminer s'il faut prendre des mesures afin de protéger la santé et la sécurité de la population canadienne. Ces mesures peuvent inclure d'avertir la population canadienne des possibles effets secondaires, de modifier l'utilisation recommandée du produit ou de retirer le produit du marché.

Les personnes chez qui un EIAV se produit devraient le signaler à un professionnel de la santé. Les professionnels de la santé doivent remplir le Formulaire de rapport des effets secondaires suivant l'immunisation qui convient pour leur province ou leur territoire et l'acheminer aux autorités de santé publique de la région.

Q7. Qu'en est-il si un événement indésirable associé à un vaccin (EIAV) est signalé?

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Santé Canada est résolu à protéger la santé et la sécurité de la population canadienne et a en place un système d'examen scientifique rigoureux de l'innocuité des vaccins et de leur efficacité à prévenir les maladies qu'ils ciblent.

Avant que tout vaccin puisse être distribué au Canada, il doit être homologué au moyen du système d'examen scientifique rigoureux de Santé Canada. Santé Canada n'homologue pas un vaccin à moins que des données probantes démontrent que ses avantages l'emportent sur ses risques. Les programmes de santé publique au Canada recommandent de nombreux vaccins pour empêcher les gens de contracter des maladies. Ces vaccins sont administrés à de grandes quantités de personnes en santé. C'est pourquoi il est particulièrement important de réglementer l'innocuité, l'efficacité et la qualité des vaccins. Les événements indésirables associés aux vaccins (EIAV) vont de réactions bénignes (p. ex. courbatures, contusions, légers maux de tête) jusqu'à de très rares réactions graves (p. ex. paralysie, atteintes nerveuses). En plus de l'examen scientifique, il y a aussi des systèmes de production de rapports en place pour la surveillance de l'innocuité des vaccins en continu.

Une fois que la vente d'un vaccin est autorisée, les fabricants ont l'obligation de continuer de présenter de l'information sur l'innocuité et l'efficacité de ce vaccin, de surveiller et de signaler tout EIAV possible ainsi que de prendre des mesures pour atténuer les risques. Santé Canada n'hésitera pas à intervenir dans l'éventualité où un nouveau problème touchant l'innocuité est découvert ou si un problème connu s'aggrave.

Toute personne qui est témoin ou qui subit un effet secondaire associé à un vaccin est vivement encouragée à le déclarer à un professionnel de la santé. Les professionnels de la santé ont l'obligation de déclarer les EIAV aux autorités de santé publique de la région. Les autorités de santé publique les signalent ensuite à l'Agence de la santé publique du Canada (ASPC).

Les déclarations d'EIAV transmises à l'ASPC par les administrations fédérale, provinciales et territoriales (FPT) sont rassemblées dans le Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI). Les déclarations d'événements indésirables graves sont présentées à l'ASPC dans les sept jours suivant leur réception par les administrations. Les administrations FPT déclarent aussi à l'ASPC tout signalement de décès dans les 24 heures suivant leur prise de connaissance de la situation. Les déclarations d'événements indésirables graves sont traitées le jour ou le lendemain de leur communication, et l'examen du dossier médical s'amorce dans les trois jours suivant la fin du traitement des données. Si les nombres ou les taux d'EIAV dépassent les nombres ou les taux de fond établis en fonction des normes internationales, un avertissement en matière d'innocuité sera diffusé, ce qui entraînera la prise de diverses mesures. Ces mesures peuvent inclure d'avertir la population canadienne des possibles effets secondaires, de modifier l'utilisation recommandée du produit ou de retirer le produit du marché.

Q8. Quelle forme prendra un programme de soutien en cas de lésions causées par un vaccin?

L'Agence de la santé publique du Canada (ASPC), en collaboration avec les provinces et les territoires, travaille actuellement à la mise en œuvre d'un programme de soutien en cas de lésions causées par un vaccin (PSLV) pancanadien sans égard à la responsabilité. L'établissement d'un PSLV permettra au Canada de renforcer sa stratégie globale en matière de vaccination, ce qui l'aidera à demeurer concurrentiel quant à l'accès aux nouveaux vaccins au fur et à mesure qu'ils sont offerts et, en définitive, à protéger la population canadienne. Cette

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mesure permettra aussi au Canada de se mettre au diapason de ses homologues du G7, qui offrent tous un PSLV national.

Comme la portée de ce programme fait actuellement l'objet de discussions avec les provinces et les territoires, aucun autre détail ne peut être divulgué pour le moment.

Q9. L'innocuité d'un vaccin fait-elle l'objet d'une surveillance de la part du gouvernement du Canada après son homologation?

Le Canada dispose d'un système robuste et bien établi de surveillance des vaccins. Une fois un vaccin sur le marché, Santé Canada et l'Agence de la santé publique du Canada surveilleront les effets indésirables après l'immunisation, en collaboration avec les provinces, les territoires et le fabricant.

La base de données Canada Vigilance de Santé Canada est le programme canadien de surveillance des vaccins sur le marché qui permet de recueillir et d'évaluer les signalements d'effets indésirables présumés pour les produits de santé vendus au Canada. La surveillance des produits offerts sur le marché permet à Santé Canada de surveiller le profil d'innocuité de produits de santé une fois qu'ils sont sur le marché pour veiller à ce que les avantages continuent de l'emporter sur les risques.

Les fabricants de vaccins sont tenus de continuer à recueillir des données sur l'innocuité et l'efficacité à long terme de leurs produits. Pfizer et BioNTech, par exemple, feront un suivi des participants des essais cliniques pendant au moins deux ans après l'administration de la deuxième dose du vaccin. Santé Canada continuera d'évaluer toutes les données accessibles sur l'innocuité des vaccins provenant des études cliniques et de la surveillance après la mise en marché et n'hésitera pas à prendre les mesures appropriées, le cas échéant, pour protéger la santé et la sécurité des Canadiens, notamment, avertir la population canadienne des possibles effets secondaires, modifier l'utilisation recommandée du produit ou même retirer le produit du marché.

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Media Lines

Testing positive for COVID-19 after one dose of the vaccine

Issue Statement: Media have reported on multiple individuals who have tested positive for COVID-19 despite having been vaccinated. Media attention on these scenarios is expected to continue. These media lines explain how such a situation may arise.

Key Messages:

- There are multiple reasons a person may become infected with COVID-19 after being vaccinated. A person may have been previously exposed to the virus or exposed shortly after vaccination, before the body has had time to create an immune response.
- Health Canada authorized the Pfizer-BioNTech and Moderna vaccines as two-dose regimens.
- The immune system usually requires 7-14 days after vaccination to begin to create a response that offers protection against COVID-19. A vaccine is thought to offer maximum protection 14 days after the second dose.
- Clinical trails data indicates that both approved vaccines are 95% effective after two doses; however, they are not 100% effective. This means they may not work for a small percentage of recipients.

On asymptomatic infections before vaccination:

- Symptoms can take up to 14 days to appear after exposure to the virus, and some people never develop symptoms at all (asymptomatic). This means it's possible to be unknowingly infected with COVID-19 before vaccination.
- Those who are infected with the virus at the time they are given the vaccine, or shortly thereafter, are unlikely to be protected by the vaccine, as the immune system usually requires 7-14 days to build a response.
- However, someone who was previously infected by the COVID-19 virus but is no longer infected can be immunized to help protect against possible future disease.

On the time needed to build an immune response after vaccination:

- The immune system usually requires 7-14 days after vaccination to create a response that offers protection against COVID-19. A vaccine is thought to offer maximum protection 14 days after the second dose.
- This means that it's possible to become infected within the first 14 days following vaccination, before the body has a chance to create an effective immune response
- The majority of participants in the Pfizer-BioNTech COVID-19 vaccine clinical trial received the second dose 21 to 27 days apart, and efficacy analyses in the Pfizer-

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BioNTech clinical trial included participants who received their second dose 19-42 days after their first dose.

- Efficacy analyses in the Moderna clinical trial included participants who received their second dose 22 to 42 days after their first dose.

Questions and Answers

Q1. If the second dose is not administered within Health Canada's authorized dosing regimen, should Canadians still receive that second dose?

If administration of the second dose of a COVID-19 vaccine is delayed, the second dose should still be given as soon as possible. People do not need to restart a vaccine series as a result of delays between doses. That's because those delays do not generally reduce the final immune response in most multi-dose vaccine products.

Q2. Can a vaccinated person get COVID-19?

The currently authorized COVID-19 vaccines have demonstrated safety and high efficacy (approx. 95%), in the short term, against symptomatic laboratory-confirmed COVID-19 disease from one to two weeks after receiving the full two-dose series. However, as the vaccines are not 100% effective, they may not work for a small percentage of recipients.

Q3. Can vaccinated people spread the virus to others?

There is limited evidence on whether someone who received the vaccine is still able to spread the virus. Everyone must continue following public health measures, regardless of vaccination with COVID-19 vaccines, to protect themselves, their loved ones, as well as people and communities at risk of more severe disease or outcomes from COVID-19. To do this, you need to continue to:

- Follow the guidance of your local public health authority
- Stay home and isolate if you have any symptoms of COVID-19, even if mild
- Limit close contacts to only those in your immediate household
- Maintain a physical distance from people outside of your immediate household
- Avoid the 3C's as much as possible: closed spaces, crowded places, and close interactions (e.g., close-range conversations). Risk is higher in settings where these factors overlap or involve activities such as singing, shouting or heavy breathing (e.g., during exercise).
- Practice regular hand hygiene, respiratory etiquette and avoid touching your eyes, nose and mouth
- Clean and disinfect your personal surfaces and objects
- Limit your outings to only essential activities, especially if you are at risk of more severe disease or outcomes from COVID-19
- Wear a non-medical mask, in situations and settings where they are recommended
- Reduce personal non-essential travel

Q4. Is it true that you can get COVID-19 from the vaccine?

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No, you can't get COVID-19 from the vaccine. Many vaccines are being studied to see if they will prevent COVID-19, and Health Canada is expediting reviews of all COVID-19 vaccine submissions.

Some of the vaccine candidates (including AstraZeneca and Janssen) that are most advanced in development are viral vector-based vaccines. These types of vaccines use a harmless virus (in this case, the adenovirus that can cause the common cold) as a delivery system. The vector virus used is not the virus that causes COVID-19.

Once injected into the body, the virus contained within the vaccine produces the SARS-CoV-2 spike protein. It does its job and then goes away. Through this process, the body is able to mount a strong immune response against the spike protein without exposing you to the virus that causes COVID-19.

The two vaccines currently authorized in Canada are messenger RNA vaccines (called mRNA vaccines). mRNA vaccines are a new type of vaccine that don't contain viruses or bacteria. Instead, they contain instructions that teach our cells how to make antigen proteins that will trigger an immune response. Once triggered, our body then makes antibodies and other immune responses. These immune responses help us fight the infection to prevent us from getting sick. You can't get infected from mRNA vaccines.

Q5. Could the antibodies from the COVID-19 vaccine result in a false positive test result?

Two kinds of tests are currently available for COVID-19:

- A test for active infection (diagnostic) that tells you if you have a current COVID-19 infection. This is done using a swab from your nose or throat, or a saliva sample. These tests are expected to continue to perform accurately in vaccinated individuals.
- An antibody (serology) test tells you if you, at some point, were exposed to the virus and had a COVID-19 infection. These tests can also identify if a person was vaccinated. They are not used to diagnose a current COVID-19 viral infection. This test is done using a sample of your blood.

For more information on testing, visit Canada.ca/coronavirus.

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From: Bent, Stephen (PHAC/ASPC)
Sent: 2021-04-29 4:20 PM
To: Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Thompson, Kathy (PHAC/ASPC)
Cc: Elmslie, Kim (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Guild, Sara (HC/SC); Diogo, Brigitte (PHAC/ASPC); Parisien, Stéphanie (PHAC/ASPC)
Subject: Injury Compensation

Hi,

As mentioned on the call, **individuals who cross the Border to the US would not be eligible for VISP based on current policy authorities**. There are only a few minor exemptions (CAF and Foreign Service members).

However, the US does have a **Countermeasure Injury Compensation Program** that handles injury claims for COVID vaccines.

Based on my quick review of the **US government website**, **citizenship is not a requirement to access the US program**. So individuals who meet the other eligibility requirements for the US program should be able to apply to it.

To note, our program isn't citizenship-based either. A US citizen who gets vaccinated here in Canada would be covered under our program.

Steve

Stephen Bent
(he | il)

Director General | Directeur général
Centre for Immunization and Respiratory Infectious Diseases |
Le Centre de l'immunisation et des maladies respiratoires infectieuses
Public Health Agency of Canada |Agence de la santé publique du Canada
Stephen.Bent@Canada.ca
613-851-2702

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From: Mitchell, Heloise (HC/SC)
Sent: 2020-12-14 2:28 PM
To: Ministerial Services / Services Ministériels (HC/SC); Elmslie, Kim (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Aung-Thin, Pamela (HC/SC); HC.F CPAB ADMO Advisors F.SC; Smith4, Melissa (HC/SC); LeSage, Lynn (HC/SC); Price, Brenda (NRCAN/RNCAN); Lewis, Roxanne (HC/SC); Fontaine, Marie-Pier (HC/SC); Reid, Carrie (HC/SC)
Cc: Raymond, Barbara (PHAC/ASPC); Hartigan, Maureen (HC/SC); Simoneau2, Chantal (PHAC/ASPC); Gaudreau, Marc-Andre (PHAC/ASPC); Archibald, Chris (PHAC/ASPC); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); HC.F Comms_Coordination F.SC; Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); Earley, Jaimie (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); Nguyen, Jennifer (HC/SC); Richer, Andrea (HC/SC); Aylward, Brett (HC/SC); Ouellette, Francis (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Marchand, Katrina (HC/SC); Demaine, Erika (HC/SC)
Subject: RE: For RUSH ADM/VP Approval: Web | VISP
Attachments: WEB_Vaccine Injury Support Program 2020_12_14_1348 HM PAT.docx

Hello,

Pam`s approved version is attached. The revisions help line up the proposed web content with the NR content.

Thank you,

Heloise Mitchell
Communications Executive/Gestionnaire des communications
Office of the Assistant Deputy Minister, CPAB/Bureau de la sous-ministre adjointe, DGAPC
Health Canada/Santé Canada
Tel: 613-960-2174
Cell: 613-617-8224

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-14 1:51 PM
To: Elmslie, Kim (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; Aung-Thin, Pamela (HC/SC) ; HC.F CPAB ADMO Advisors F.SC ; Smith4, Melissa (HC/SC) ; LeSage, Lynn (HC/SC) ; Price, Brenda (HC/SC) ; Lewis, Roxanne (HC/SC) ; Fontaine, Marie-Pier (HC/SC) ; Reid, Carrie (HC/SC)
Cc: Raymond, Barbara (PHAC/ASPC) ; Hartigan, Maureen (PHAC/ASPC) ; Simoneau2, Chantal (PHAC/ASPC) ; Gaudreau, Marc-Andre (PHAC/ASPC) ; Archibald, Chris (PHAC/ASPC) ; Magee, Heather (HC/SC) ; Allison, Catherine (HC/SC) ; Lafkas, Cathy (HC/SC) ; Hinds, Chris (HC/SC) ; Maidment, Leanne (HC/SC) ; HC.F Comms_Coordination F.SC ; Russo, Laura (HC/SC) ; McLachlan, Kailey (HC/SC) ; Earley, Jaimie (HC/SC) ; Gearey, Jennifer (HC/SC) ; Kocent, Marissa (HC/SC) ; Payette, Louise (HC/SC) ; HPOC Communications / COPS (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; Nguyen, Jennifer (HC/SC) ; Richer, Andrea (HC/SC) ; Aylward, Brett (HC/SC) ;

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Ouellette, Francis (HC/SC) ; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC ; Marchand, Katrina (HC/SC) ; Demaine, Erika (HC/SC)
Subject: For RUSH ADM/VP Approval: Web | VISP
Importance: High

Good afternoon,

Please see attached web content for your approval by 3:00pm. Apologies for the rush - we are aiming to post today or tomorrow morning.

Thank you,
Amanda

Issue: In early December 2020, the Public Health Agency of Canada began consulting with provinces and territories on establishing a pan-Canadian Vaccine Injury Support Program (VISP). The attached web content is for promoting the new VISP to Canadians.

Approvals:
Simone Gobeil, Mgr (Dec 12, 2020)
Stephen Bent, DG (Dec 12, 2020)
[redacted]
Megan Bettle, DG, HPFB (Dec 12)
**Web plain language review*
HPOC CHOPS and EM (Dec 13)
Heather Magee, Director, CPAB PCRT (FYI)
Cathy Allison, DG, CPAB vaccine communications (Dec 14)
Dr. Njoo and/or Kim Elmslie (pending)
Pam Aung-Thin, a/ADM, CPAB (pending)
HPFB ADMO (pending)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
DMO (pending)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing

Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856

Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856

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***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et*

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les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Support ~~Program~~

Vaccine Injury Support ~~Program~~

Health Canada:

- only approves vaccines in Canada after a thorough and independent review of the scientific evidence
- closely monitors once a vaccine is on the market and can quickly have it removed if safety concerns are identified

~~Even with the high standards set for vaccine safety, a small number of people may experience a serious permanent injury as a result of receiving a vaccine.~~ It's extremely rare to have a serious reaction to a vaccine ~~that leads to a serious permanent injury~~. ~~However~~Even with the high standards set for vaccine safety, a small number of ~~people may~~ Canadians may experience an adverse event following immunization, caused by vaccines or their administration~~experience a serious permanent injury as a result of receiving a vaccine.~~

On December 10, 2020, the Public Health Agency of Canada (PHAC)~~Government of Canada~~ announced that it ~~will~~ would implement a pan-Canadian no-fault vaccine injury support program~~create a Vaccine Injury Support Program~~. The program will provide financial support to people in the rare event that they experience an adverse reaction to a vaccine ~~who experience a serious permanent injury after receiving a vaccine approved~~ authorized by Health Canada ~~for sale in Canada~~. Provinces and territories will be consulted in the development of this program, which will be modelled after Quebec's existing program. This program will bring Canada in line with a growing number of countries ~~who~~ that have similar programs.

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Commented [HM1]: I`d suggest removing the "serious permanent injury" reference—it`s not in the NR and is probably not content we would want to lead with. I`ve reworded content to be more consistent with the NR.

Commented [PA2R1]: agreed

Commented [HM3]: NR wordin

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From: Smith4, Melissa (HC/SC)
Sent: 2020-12-14 2:24 PM
To: Ministerial Services / Services Ministériels (HC/SC); Elmslie, Kim (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Aung-Thin, Pamela (HC/SC); HC.F CPAB ADMO Advisors F.SC; Lewis, Roxanne (HC/SC)
Cc: Raymond, Barbara (PHAC/ASPC); Hartigan, Maureen (HC/SC); Simoneau2, Chantal (PHAC/ASPC); Gaudreau, Marc-Andre (PHAC/ASPC); Archibald, Chris (PHAC/ASPC); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); HC.F Comms_Coordination F.SC; Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); Earley, Jaimie (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); Nguyen, Jennifer (HC/SC); Richer, Andrea (HC/SC); Aylward, Brett (HC/SC); Ouellette, Francis (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Marchand, Katrina (HC/SC); Demaine, Erika (HC/SC)
Subject: RE: For RUSH ADM/VP Approval: Web | VISP
Attachments: WEB_Vaccine Injury Support Program 2020_12_14_1348_HPFB.docx

Approved by Supriya with one tweak for consideration in the HC section at the top.
Melissa

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-14 1:51 PM
To: Elmslie, Kim (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; Aung-Thin, Pamela (HC/SC) ; HC.F CPAB ADMO Advisors F.SC ; Smith4, Melissa (HC/SC) ; LeSage, Lynn (HC/SC) ; Price, Brenda (HC/SC) ; Lewis, Roxanne (HC/SC) ; Fontaine, Marie-Pier (HC/SC) ; Reid, Carrie (HC/SC)
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Subject: For RUSH ADM/VP Approval: Web | VISP
Importance: High

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Amanda

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Approvals:
Simone Gobeil, Mgr (Dec 12, 2020)
Stephen Bent, DG (Dec 12, 2020)
[redacted]
Megan Bettle, DG, HPFB (Dec 12)
**Web plain language review*
HPOC CHOPS and EM (Dec 13)
Heather Magee, Director, CPAB PCRT (FYI)
Cathy Allison, DG, CPAB vaccine communications (Dec 14)
Dr. Njoo and/or Kim Elmslie (pending)
Pam Aung-Thin, a/ADM, CPAB (pending)
HPFB ADMO (pending)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
DMO (pending)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing
Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856
Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856
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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Support Program

Vaccine Injury Support Program

Health Canada:

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- closely monitors once a vaccine is on the market and can quickly have it removed if safety concerns are identified

Even with the high standards set for vaccine safety, a small number of people may experience a serious permanent injury as a result of receiving a vaccine. It's extremely rare to have a serious reaction to a vaccine that leads to a serious permanent injury.

On December 10, 2020, the Government of Canada announced it will create a Vaccine Injury Support Program. The program will provide financial support to people who experience a serious permanent injury after receiving a vaccine approved by Health Canada for sale in Canada. Provinces and territories will be consulted in the development of this program, which will be modelled after Quebec's existing program. This program will bring Canada in line with a growing number of countries who have similar programs.

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From: Smith4, Melissa (HC/SC)
Sent: 2020-12-10 2:18 PM
To: Ministerial Services / Services Ministériels (HC/SC); HC.F CPAB ADMO Advisors F.SC; Aung-Thin, Pamela (HC/SC); Njoo, Howard (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC); HPOC EM / GU COPS (PHAC/ASPC); Lewis, Roxanne (HC/SC)
Cc: Raymond, Barbara (PHAC/ASPC); Hartigan, Maureen (HC/SC); Simoneau2, Chantal (PHAC/ASPC); Gaudreau, Marc-Andre (PHAC/ASPC); Archibald, Chris (PHAC/ASPC); Hussen, Hayat (PHAC/ASPC); Lalonde, Edith (PHAC/ASPC); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); HC.F Comms_Coordination F.SC; Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); Earley, Jaimie (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); Nguyen, Jennifer (HC/SC); Richer, Andrea (HC/SC); Aylward, Brett (HC/SC); Ouellette, Francis (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Allison, Catherine (HC/SC); Magee, Heather (HC/SC); Demaine, Erika (HC/SC); McLachlan, Kailey (HC/SC); Nahum, Marilyne (HC/SC); Lafkas, Cathy (HC/SC)
Subject: RE: For RUSH ADM/VP approval: NR | Vaccine Injury Support Program (VISP)
Attachments: PHAC_ML_VISP_2020-12-08_910-tracked_hpfb.docx

Hi – no concerns with the NR. Attached are comments on the Qs&As.
Melissa

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-10 1:33 PM
To: HC.F CPAB ADMO Advisors F.SC ; Aung-Thin, Pamela (HC/SC) ; Njoo, Howard (PHAC/ASPC) ; Elmslie, Kim (PHAC/ASPC) ; HPOC EM / GU COPS (PHAC/ASPC) ; Smith4, Melissa (HC/SC) ; LeSage, Lynn (HC/SC) ; Price, Brenda (HC/SC) ; Lewis, Roxanne (HC/SC) ; Fontaine, Marie-Pier (HC/SC) ; Reid, Carrie (HC/SC)
Cc: Raymond, Barbara (PHAC/ASPC) ; Hartigan, Maureen (PHAC/ASPC) ; Simoneau2, Chantal (PHAC/ASPC) ; Gaudreau, Marc-Andre (PHAC/ASPC) ; Archibald, Chris (PHAC/ASPC) ; Hussen, Hayat (PHAC/ASPC) ; Lalonde, Edith (PHAC/ASPC) ; Magee, Heather (HC/SC) ; Allison, Catherine (HC/SC) ; Lafkas, Cathy (HC/SC) ; Hinds, Chris (HC/SC) ; Maidment, Leanne (HC/SC) ; HC.F Comms_Coordination F.SC ; Russo, Laura (HC/SC) ; McLachlan, Kailey (HC/SC) ; Earley, Jaimie (HC/SC) ; Gearey, Jennifer (HC/SC) ; Kocent, Marissa (HC/SC) ; Payette, Louise (HC/SC) ; HPOC Communications / COPS (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; Nguyen, Jennifer (HC/SC) ; Richer, Andrea (HC/SC) ; Aylward, Brett (HC/SC) ; Ouellette, Francis (HC/SC) ; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC ; Allison, Catherine (HC/SC) ; Magee, Heather (HC/SC) ; Demaine, Erika (HC/SC) ; McLachlan, Kailey (HC/SC) ; Nahum, Marilyne (HC/SC) ; Lafkas, Cathy (HC/SC)
Subject: For RUSH ADM/VP approval: NR | Vaccine Injury Support Program (VISP)
Good afternoon,

ATIA - 23

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Please see attached products for your approval by 3pm, if possible. We understand that the aim is to post the news release at 5pm today.
The media lines, web content and comms approach were previously approved but have been revised. Tracked and clean versions are attached.
This is with HPCO ChOps for concurrent approval given the urgency.
Thank you,
Amanda

Issue: In early December 2020, the Public Health Agency of Canada began consulting with provinces and territories on establishing a pan-Canadian Vaccine Injury Support Program (VISP). The intention to pursue this program would be announced at the First Minister's Meeting December 10, 2020 (TBC).

NR Approvals:
Simone Gobeil, Mgr (Dec 10)
Stephen Bent, DG (Dec 10)
[redacted]
Megan Bettle, DG, HPFB (Dec 10)
HPOC ChOps (pending)
Heather Magee, Director, CPAB PCRT (FYI)
Cathy Allison, DG, CPAB vaccine communications (FYI)
Dr. Njoo and/or Kim Elmslie (pending)
Pam Aung-Thin, a/ADM, CPAB (pending)
HPFB ADMO (pending)
HPOC EM (pending)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
Cindy Evans, VP (FYI)
DMO (FYI)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing
Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856
Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856
***Please note** emails to Comms_Coordination@canada.ca are monitored from 7am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*
***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Public Health Agency of Canada | Agence de la santé publique du Canada

Media Lines –

Vaccine Injury ~~Compensation program~~Support Program

Issue: In early December 2020 ~~(date TBD),~~ the Public Health Agency of Canada ~~will begin~~began consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program.

~~Web content is being developed to reference these consultations. Messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.~~

The intention to pursue this program would be announced at the Health Minister's Meeting in December, 2020 (TBC). A previously approved holding line is recommended to be used, should media inquire in advance of this announcement.

Holding line until announced:

Vaccination protects individuals from vaccine-preventable diseases. At the same time, it helps protect families, close contacts, communities, and society as a whole. Notwithstanding the rigour of clinical trials and excellence in vaccine delivery, a small number of Canadians will experience an adverse event following immunization, caused by vaccines or their administration. Vaccine injury compensation programs can play an important role in strengthening immunization programs by compensating people who suffer a serious vaccine injury quickly and fairly, without having to incur the additional burden of litigation.

Quebec is the only jurisdiction in Canada that has a vaccine injury compensation program. Vaccination is a shared responsibility among the federal, provincial and territorial governments, and the federal government is continuing discussions with provinces and territories on this matter.

Upon Announcement - Key messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC), is establishing a pan-Canadian no-fault vaccine injury ~~compensation (VIC)~~support program, (VISP), in consultation with the provinces and territories.
- This will strengthen national immunization campaigns by ensuring equitable access/ and coverage to vaccines for all individuals immunized in Canada.
- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from a serious adverse reaction to a vaccine. This is extremely rare – less than one in a million.

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- In the very rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement – they deserve fair compensation.
- Establishing a ~~VIC~~VISP program as part of Canada's broader vaccination strategy ~~and~~ will help ensure that we remain competitive in accessing new vaccines as they become available, and ultimately protect Canadians.
- It also brings Canada in line with its G7 counterparts that all provide ~~VIC~~vaccine injury compensation protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.
- As the scope of this program is still under discussion with the Provinces and Territories, no further details can be disclosed at this time.

If pressed on state of FPT discussions:

Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury ~~compensation (VIC)~~support program (VISP).

If pressed on timing:

The establishment of a vaccine injury compensation program has been previously identified as an area of importance by the Government of Canada, the provinces and territories, to ensure that Canadians who support public health by being immunized are supported themselves in the rare event they are injured.

If pressed on whether provinces and territories choose to not participate:

Health care is a matter of provincial and territorial jurisdiction. The Public Health Agency of Canada is establishing a pan-Canadian no-fault vaccine injury support program for those provinces and territories who wish to opt-in.

Questions and Answers:

Q1. Does the Government of Canada have confidence in the COVID-19 vaccines for which it has advance purchase agreements?

Vaccines are a critical way to limit the spread of the virus. They are effective and safe for protecting our health, as well as the health of family and community members. ~~Health Canada is committed to protecting the health and~~ The safety of Canadians ~~and has a rigorous scientific review system in place to assess~~ is our first and foremost priority. While vaccines ~~for safety and effectiveness in preventing the diseases they target. The department will not authorize any drug or~~ in the past have taken years to come to market, thanks to advances in science and technology, a focused federal response, and an unprecedented level of global cooperation, a COVID-19 vaccine ~~unless evidence demonstrates that its benefits outweigh the risks~~will be available much faster than was previously possible.

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Health Canada received Pfizer's submission on October 9, 2020. The vaccine was authorized under Health Canada's Interim Order Respecting the Importation, Sale and ~~that it meets stringent safety~~Advertising of Drugs for Use in Relation to COVID-19. The Interim Order allows Health Canada to expedite the review and approval of COVID-19 drugs and vaccines, while maintaining Canada's high standards for safety, efficacy and quality ~~requirements. Health Canada continues to~~.

Under the Interim Order, Health Canada can accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess information submitted by the manufacturer as it becomes available during the product development process. This new process still involves reviewing all the necessary data thoroughly to support authorization ~~and conducting any necessary testing of samples~~.

The authorization was primarily supported by safety and efficacy data from a ~~late-stage~~ randomized, double-blind, placebo-controlled phase 2/3 clinical trial involving about 44,000 participants. Safety was also supported by the results of an earlier ~~stage~~ trial conducted in Germany and the U.S. that showed participants had an appropriate immune response, and that the vaccine was well tolerated.

Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor ~~their~~for any adverse events after immunization, in collaboration with the provinces and territories, international partners, and the manufacturer. As with all vaccines, Health Canada will take action if any safety ~~and effectiveness once they~~issues are ~~on the market~~identified. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information. The Pfizer-BioNTech vaccine was authorized with terms and conditions that require the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure the benefits of the vaccine continue to be demonstrated through market use.

Q2. What is the likelihood of a possible adverse events following immunization?:

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g. muscle aches, bruising, mild headache, etc) to

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Commented [MS1]: This is not correct under the Interim Order – it's the regular process, but under the IO it's different.

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very rare but serious adverse events (e.g. paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and effectiveness of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Q2. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

Commented [MB2]: Suggest this start with a line about vaccines being very safe.

Canada has a robust and well-established vaccine surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

Health Canada will continue to review all the available safety data from ongoing clinical studies and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information.

Q3. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

~~HC~~Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs in order to ensure they can be sold.

At this time, we cannot disclose details of specific agreements in an effort to protect our negotiating position and commercially sensitive pricing information, as well as to respect confidentiality clauses in our vaccine agreements.

Q4. What will a ~~Vaccine Injury Compensation Program~~vaccine injury compensation program look like?

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The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury ~~compensation (VIC)~~support program, (VISP), in consultation with the provinces and territories. Establishing a ~~VIC~~VISP program will strengthen Canada's broader vaccine strategy will help ensure that Canada remains competitive in accessing COVID-19 vaccines and other new vaccines as they become available, and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national ~~VIC~~vaccine injury compensation programming in place.

As the scope of this program is under discussion with the Provinces and Territories, no further details can be disclosed at this time.

Q5. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Commented [MB3]: Reframed as this is very repetitive

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization ~~and conducting any necessary testing of samples~~, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. ~~This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.~~

~~While every effort is being made in Canada to expedite COVID-19 vaccine development, safety, efficacy and quality will not be compromised.~~ COVID-19 vaccine(s) ~~will be~~are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

~~Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.~~

Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q6. How can Canadians be sure the vaccine will be safe if we don't have the same 10-year period as with other vaccines?

Commented [MB4]: I would remove this whole question – there's nothing new here that isn't in the question above

The 10-year timeline that is often quoted as the time required to develop a vaccine reflects

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sequential steps of pre-clinical development and separate phases of clinical trials, as well as the time needed for vaccine manufacturers to fund trials and develop their manufacturing processes. Significant research and development funding is allowing vaccine developers to greatly accelerate their processes.

The use of adaptive clinical trials, which allow ongoing assessment of data and moving from one phase to the next without large gaps, allows more rapid collection of data from clinical trials.

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization and conducting any necessary testing of samples, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.

After a vaccine is granted market authorization, Health Canada and the Public Health Agency of Canada have a joint role in monitoring its safety and effectiveness, along with vaccine manufacturers and provincial/territorial public health authorities. Enhanced monitoring systems will be in place for all COVID-19 vaccines.

Q7. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases.

Addressing vaccine hesitancy is a priority for the Government of Canada. Efforts to inform and educate Canadians to help build vaccine confidence have been part of PHAC's regular business for years.

For example, from 2017 to 2019, the PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant, to debunk misinformation on vaccine safety and importance. PHAC also leads an annual seasonal flu immunization campaign targeting groups, such as seniors over 65 who are especially vulnerable. A subsequent childhood vaccination campaign will launch early in 2021, with similar goals and objectives to the previous one. Similar communications strategies will be used when a new COVID-19 vaccine is released to ensure that Canadians have the proper information to inform their choice to receive the vaccine when available. These campaigns use different approaches to reach different segments of the public, including advertising, public education and outreach. PHAC works with many partners, including provinces and territories and professional associations to implement these strategies.

The Chief Public Health Officer, Dr. Theresa Tam is also working with chief medical officers of health from all provinces and territories through the Special Advisory Committee and together they will work with public health staff across all jurisdictions in Canada to combat misinformation

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and concerns around the release of a new COVID-19 vaccine.

DRAFT

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From: Elmslie, Kim (PHAC/ASPC)

Sent: 2021-02-03 8:26 AM

To: Stewart, Iain (PHAC/ASPC)

Cc: Rendall, Jennifer (PHAC/ASPC); Krumins, Martin (PHAC/ASPC); Bent, Stephen (PHAC/ASPC); Parisien, Stéphanie (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Njoo, Howard (PHAC/ASPC)

Subject: Update Vaccine Injury Support Program

Am providing latest on steps to March 15th selection of VISP administrator.

[redacted]

3rd Party Deliverers

- Informal outreach has begun to potential delivery organizations
- Meeting with four organizations this week.

Key Next Steps

- [redacted]
- Update PTs (email when ISFR goes up) and SAC and CDMH.
- Update DM VRO

Kim

Kimberly Elmslie

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Vice-President/vice-président

Infectious Disease Prevention and Control Branch/Direction-générale de la prévention et du contrôlée des maladies infectieuses

Public Health Agency of Canada/L'agence de la santé publique du Canada

Sent from my iPhone

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From: Elmslie, Kim (PHAC/ASPC)
Sent: 2021-01-21 6:44 PM
To: Stewart, Iain (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC)
Cc: Njoo, Howard (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Bent, Stephen (PHAC/ASPC); Levesque2, Kaili (HC/SC)
Subject: Update on Vaccine Immunity Support Program
Attachments: Update VISP - Jan 20.ppt

With thanks to Stephen and his team, please find attached a short update deck on the implementation of VISP.

Follow-up is underway with the outstanding jurisdictions (NB, PEI, AB, SK) bilaterally to confirm their participation in the federal program. Concurrently we have been consulting with the Government of Quebec to better understand how their program operates, and working closely with the CFO's team and TBS on finalizing Terms and Conditions for the program for approval. For the Terms and Conditions, there is an expedited process that TBS has put in place for COVID-19 initiatives that we can access.

[redacted]

Kim

Kimberly Elmslie
Vice-President/vice-présidente
Infectious Disease Prevention and Control Branch/Direction-générale de la prévention et du contrôle des maladies infectieuses
Public Health Agency of Canada/L'agence de la santé publique du Canada

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From: Krumins, Martin (PHAC/ASPC)
Sent: 2021-02-25 2:34 PM
To: Stewart, Iain (PHAC/ASPC)
Cc: Elmslie, Kim (PHAC/ASPC); Njoo, Howard (PHAC/ASPC)
Subject: [redacted]

[redacted]

Martin

Martin Krumins
(he/him) (il/lui)
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From: Denis, Joel (PHAC/ASPC)
Sent: 2020-11-30 10:01 AM
To: Njoo, Howard (PHAC/ASPC); Bent, Stephen (PHAC/ASPC)
Cc: Romano, Anna (PHAC/ASPC); Anderson3, Jennifer (PHAC/ASPC); Renee David; Lamarre, Catherine (PHAC/ASPC)
Subject: Vaccine Immunization Compensation Program
Attachments: lettre IVV QC Nov 27 FR.docx; EN_VIC SAC Deck Revised Nov 26.pptx; Draft VP sps for VIC at SAC - 2020-11-26.docx; VIC critical path MINO 2020-11-27.docx

---

Bonjour Howard et Stephen,

In advance of tomorrow's briefing with you on the vaccine immunization program and next steps, we wanted to provide you with key docs:
-critical path
-letter to QC following your call
-deck and key messages for this week's SAC presentation

And key upcoming milestones:
-Briefing with Howard Tuesday, December 1 at 9:30am
-Howard to call Quebec Tuesday or Wednesday – we'll draft key messages for your consideration
-Briefing with Minister's office Wednesday, December 2 – we are drafting docs for your consideration
-Howard to brief SAC on Thursday December 3 – deck and key messages are attached

[redacted]

Merci bien.

Joël

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Meeting with Special Advisory Committee (SAC) December 3, 2020 (TBC)

Speaking Points for Vice-President of the Infectious Disease Prevention and Control Branch

CONTEXT

OBJECTIVE AND DISCUSSION FORMAT:

IDPCB VP will inform SAC members of the federal government's intent to implement a pan-Canadian no-fault Vaccine Injury Compensation program in the coming months.

A deck will be presented outlining the proposed program and forward plan, and a discussion will follow.

1. No-fault Vaccine Injury Compensation in Canada

Context: Recognizing that vaccination is an area of shared jurisdiction, a deck will be presented to inform provincial and territorial stakeholders of the federal intent to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program, while also acknowledging that both timing and communication of this program may impact public perceptions pertaining to an eventual COVID-19 vaccine. Next steps will be presented and discussed including but not limited to, support for clear and aligned messaging, opt-out options and federal funding for provincial programs that meet federally-established criteria.

The federal VIC program intends to draw lessons from Quebec's established and successful VIC program for its design and implementation.

Slide 2: Purpose and overview of presentation

- Today, I want to advise the table that the Government of Canada intends to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program to cover all Health Canada-approved vaccines administered as of

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January 1, 2021. There will be an opportunity for provinces or territories to opt out and administer a similar program, which I will talk about further in the presentation.

- I would also like to obtain your views and thoughts on how best to implement this program within the context of the COVID-19 vaccine roll out.

Slide 3: VIC program drivers

- Four key drivers are prompting this action now. There have been previous FPT discussions on VIC programming in the context of the National Immunization Strategy but it ultimately did not move forward.

- We now have an opportunity to close a long-standing gap, and implement a federal pan-Canadian program. We recognize that Quebec has provided leadership in this area, and we wish to see all Canadians enjoy the same benefits as those who are vaccinated in Quebec.

- We will be asking Canadians to roll up their sleeves for the Covid-19 vaccine and it's only fair that they have access to a no-fault compensation program for the rare instances where serious injury does occur.

- While the ethical principles are important, we also need to ensure that we are on a level playing field with other countries. Vaccine manufacturers are increasingly considering the presence of injury compensation programs in deciding where to seek authorization for their products.

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Slide 4: Overview of VIC Program Elements

- This program would cover all vaccines approved by Health Canada. Compensation would be provided to individuals irrespective of fault, negligence, or parties involved.

- The assessment of injury causality is an essential element of the program and would be determined by an appropriate expert body.

- The only recourse currently available for Canadians outside of Quebec is to take manufacturers to court and seek damages – and to date, no court has awarded damages.

Slide 5: Overview of VIC Program Design

- The pan-Canadian program would be federally funded and administered by an arms-length Third Party. In the absence of a suitable Third Party, PHAC would be the administrator.

- We recognize that some jurisdictions may wish to administer their own program, or in the case of Quebec, continue administering their own program. There is some flexibility to opt-out, but we will need to move quickly, and once the contribution agreement with the administrator is in place, the window to opt-out with federal funding will close for the duration of the agreement (5 years, TBC).

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- Eligibility for the program would start on January 1, 2021. Canadians would have up to 3 years to file claims consistent with Quebec's requirements.

Slide 6: Key Considerations

- Canada is currently the only G7 country without a national vaccine injury compensation program and over 2 dozen countries now have some form of a program in place. We can expect the presence of a VIC to become increasingly important to vaccine manufacturers as more countries implement VIC programs.

- I realize that vaccine confidence is a topic of significant interest, and we were seized with understanding the potential impact of introducing a VIC while planning an ambitious rollout of COVID-19 vaccines.

    - We are mindful of the potential impact of announcing a VIC and have started considering communications approaches, which I will speak to in the next slide

- Very little data is available on the effect on confidence in vaccines and immunization rates following the implementation of a no-fault VIC program in other countries. We are undertaking public opinion research to ensure that we understand the impacts that a program may have on the COVID-19 vaccine deployment, and are prepared to minimize any negative effects.

- Initial research results have indicated that learning about a pan-Canadian VIC program would either have no effect or a

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positive impact on intentions to be vaccinated against COVID-19 for a large majority of Canadians.

- We're aware that timing is a consideration on how a VIC program could be perceived by the public.

Slide 7: Communications Approach

- Given the considerations at play, we have started to develop a communications approach to manage potential communications risks.

- The planned approach would be low-key and integrated into the overall vaccine rollout communications planning.

- We have prepared some proposed key messages (in the annex), and will liaise with the FPT PHN communications table to assist with the coordination of complementary messaging.

Slide 8: Proposed Next Steps

- We will be bringing this topic forward to CDMH next week, and will engage with appropriate existing tables. We do not want to introduce an overly burdensome process when you are already very busy.

- Provinces and territories will need to decide on their preferred course of action; that is, whether they wish to have their residents covered under the pan-Canadian VIC program being established or whether they would like to be supported with their own respective program, **by the end of**

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December 2020. Bilateral discussions would then ensue to discuss terms for opting out.

- **Question for the table**: any thoughts on timelines and process for indicating interest in opt-out? We were thinking a letter from PHAC President to his Deputy Minister counterparts following CDMH meeting, with the deadline for response being December 21st, in order to ensure that program can be in place by spring 2021.

- As we move forward, we plan to engage with the CIC on program design and implementation, and can return to SAC to provide updates.
  - **Question:** What are views on future discussions and updates at SAC? Would one or two updates for information be sufficient? Would the table prefer to be engaged in more substantive discussions and decisions?

Additional questions for discussion

- Does anyone have preliminary thoughts they would like to share on vaccine injury compensation?
- Any experiences in other areas that you would want us to leverage?

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DRAFT

NO-FAULT VACCINE INJURY COMPENSATION IN CANADA

Special Advisory Committee – December 1, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- To discuss provincial and territorial interests in a federally-funded pan-Canadian no-fault Vaccine Injury Compensation (VIC) program covering all Health Canada authorized vaccines or immunoglobulins that protect Canadians from vaccine preventable diseases.

Overview of the Presentation

- Vaccine Injury Compensation Program Drivers
- Overview of Program Elements
- Overview of Program Design
- Key Considerations
- Communications Approach
- Proposed Next Steps

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Vaccine Injury Compensation Program Drivers

Long-standing gap	• Establishing a national compensation program would leave a legacy of a strengthened immunization system in Canada. • Federal involvement in immunization activities and immunization safety through initiatives such as the National Immunization Strategy (2003).
Fairness and equity	• Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians. • Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.
Securing supply	• As the only G7 country without a national vaccine injury compensation program, Canada could be at a competitive disadvantage as manufacturers assess local market conditions before deciding where to market new vaccines. • Removes barriers to market entry for smaller manufacturers.
Leadership and responsibility	• Demonstrates that Canada, like other countries, recognizes that in the rare instances of serious harm due to vaccination, it is a right that individuals receive compensation. • Quebec is the only province with an established program since the 1980s, a model of leadership in this area.

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Overview of VIC Program Elements

A VIC Program would provide insurance in the event of a serious vaccine injury (e.g. permanent disability or death):

- Serves five key functions, including: receiving claims; validating claims; assessing claims to determine causality; recommending/rejecting compensation; paying claims.
- Allows fair compensation for all Canadians who are injured or harmed, not just those from one province.
- Awards compensation irrespective of fault or negligence or parties involved.
- Includes coverage for all vaccines approved by Health Canada.
- Expected to apply to measurable uninsured damages or costs.
- Causality, degree of disability and compensation to be determined by an appropriate expert body.

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Overview of VIC Program Design

- Funded by the Government of Canada and administered by a Third Party. If no suitable Third Party is identified, program will be administered by Public Health Agency of Canada.

- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts. Decisions to award compensation would be made by the Third Party, in accordance with the funding agreement.

- Intention is to use Quebec's VIC regime as the model for designing a pan-Canadian program to the extent possible, recognizing that it will not be feasible to duplicate every feature.

- Coverage will extend to all vaccines administered in Canadian territory **on or after January 1, 2021**:
  - Ensures that compensation coverage will be in place concurrently with the earliest possible date for the delivery of COVID-19 vaccine.
  - Formal program implementation, however, would follow by June 2021.

- P/Ts, including Quebec, will have the flexibility to opt out of the pan-Canadian program to administer an equivalent program, with federal funding provided if the program meets federal objectives.

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Key Considerations

Current lack of alignment with other G7 countries

- Risk that vaccine suppliers will favour countries that have no-fault VIC programs.

Effect on vaccine confidence

- **Little data** available to assess if the introduction of no-fault VIC program is associated with an increase or decrease in immunization coverage rates, either immediately or over the longer term (see Annex 3).
- Transparency on vaccine communications overall supports vaccine confidence.

Timing

- Introducing a VIC program before COVID-19 vaccine roll-out could fuel sentiment that government doubts the safety of vaccines.
- Delaying the program until COVID-19 vaccine roll-out is underway could similarly trigger concerns that a safety risk has been identified.

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Communications Approach

- Begin to introduce vaccine injury compensation into communications with Canadians now as part of updating them on COVID-19 vaccine roll-out plans.
  - Main message is the VIC puts Canada on an equal playing field with other countries and helps with Canada's competitiveness in accessing vaccines.

- Approach VIC communications by integrating it into overall vaccine roll-out planning information to Canadians (part of entire suite of efforts) rather than shining a light on it as a new program – correcting a gap in Canada's immunization policy.

- Liaise with FPT PHN communications table to assist with coordination of complementary messaging.

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Proposed Next Steps

- Engagement at key F/P/T tables, including Canadian Deputy Ministers of Health and Health Ministers (Fall 2020).
- Decision required by each P/T whether to opt-out of pan-Canadian VIC and establish equivalent program (end of December 2020).
- Integrate VIC messaging and tactics into overall vaccine communications roll-out plan and develop evidence based messages designed to motivate the appropriate behaviour (underway).
- F/P/T engagement on program design and implementation (Winter 2021).
- Solicitation of interest and award of competitive process for a Third Party administrator (Spring 2021).
- Expected program launch, accepting claims for immunizations received on or after January 1, 2021 (June 2021).

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Annexes

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Annex 1 – Sample Key Messages

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life

- Establishing a vaccine injury compensation program is part of Canada's broader vaccine strategy and will help ensure we remain competitive in accessing new vaccines as they become available
  - We need Canada to be on an equal playing field with other countries
  - This VIC program brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from an adverse reaction to a vaccine
  - This is extremely rare – less than one in a million

- In the rare event that a Canadian were to fall ill, they should not spend their time litigating in court for a settlement – they deserve fair compensation, which this program offers

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Annex 2 – What we have learned from Quebec

- Quebec's successful no-fault VIC Program could provide the scope for a **pan-Canadian regime**.
- Since its creation by legislation, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec.

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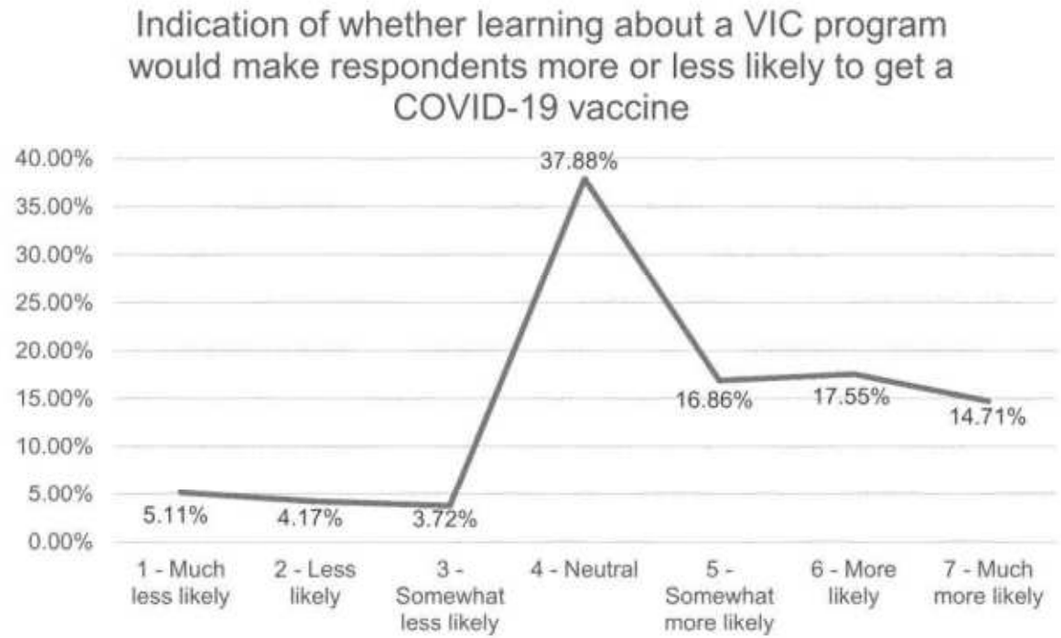
Annex 3 – Impact of VIC on Intention to Vaccinate

- Initial results from **research on the impact of learning about a national, no-fault VIC program on Canadians' intentions to be vaccinated against COVID-19*** conducted by PCO have revealed that:
  - Learning about a national VIC program **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VIC program would negatively impact their intentions to be vaccinated.



*Privy Council Office *Impact of a National, No-Fault Vaccine Injury Compensation Program on Intentions to be Vaccinated Against COVID-19: A Preliminary Analysis*, November 2, 2020. Sample size (n=1,580 Canadians).

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2020-11-27

DRAFT Critical path: Vaccine Injury Compensation Program Implementation

COVID-19 VACCINE ROLL-OUT

[redacted]

- [redacted]
- [redacted]

Milestone	Date	Deliverable
FPT Engagement		
MINO Briefing	December 2	Brief Minister's office on proposed approach with PTs prior to presenting at SAC
Engagement with Quebec (IDPCB VP)	Week of November 30	Advise Quebec of intent to implement VIC and compensate them for existing program
SAC (presenter TBC)	December 3 (TBC)	Advise of intention to establish VIC and obtain reactions
CDMH (Iain Stewart presenting)	December 16 (TBC)	
HMM (Minister Hajdu presenting)	December	
Deadline to signal opt-out	Letter sent by: December 9 Deadline: December 21	Letter from PHAC President to P/T counterparts providing deadline to opt out
Opt-out discussions	December 21-January 8 2021	Preliminary bilateral discussions to confirm scope of program and terms of funding
[redacted]		
Appointment of Third Party Administrator		
Solicitation Planning	Finalized first week of March 2021	Choice of solicitation process (open, targeted or directed) Call for proposal drafted and translated

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Milestone	Date	Deliverable
Launch Invitation to Submit Funding Request	Week of March 8, 2021	Launch of invitation to occur as soon as program authorities obtained from Treasury Board
Review submissions	Week of April 5, 2021	Submissions reviewed by qualified panel
Funding recipient identified and recommendation to President	Week of April 19, 2021	Memo to the President Funding approval Form
Contribution Agreement Signed	Week of May 3, 2021	Contribution Agreement signed by both PHAC and Third Party
Program fully implemented	**June 1, 2020**	**Applications forms are available and applicants can submit claims for compensation**

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Dr Horacio Arruda
Sous-ministre adjoint
Direction générale de la santé publique
Ministère de la santé et des services sociaux du Québec
horacio.arruda@msss.gouv.qc.ca

Docteur,

Je vous écris pour vous aviser que l'Agence de la santé publique du Canada prévoit informer les comités de gouvernance fédéraux, provinciaux et territoriaux de l'intention du gouvernement du Canada de lancer un programme pancanadien d'indemnisation des victimes d'une vaccination (IVV) sans égard à la faute. La mise en place d'un programme pancanadien d'IVV assurera une cohérence à l'échelle nationale en offrant à toutes les Canadiennes et à tous les Canadiens une couverture semblable à celle dont profitent les Québécoises et les Québécois.

Grâce au leadership de longue date du Québec, qui a mis sur pied le seul régime d'IVV au Canada, nous communiquons avec vous pour vous faire part de notre espoir de profiter de votre expérience de l'administration d'un programme d'IVV, et pour vous assurer que le gouvernement du Canada n'a aucunement l'intention de perturber le programme existant du Québec.

Nous prévoyons utiliser des éléments de votre programme d'IVV pour orienter la conception d'un programme pancanadien. Les provinces et les territoires, y compris le Québec, auront la possibilité de ne pas participer au programme pancanadien et d'établir leur propre programme financé par le gouvernement fédéral.

J'ai hâte d'en apprendre plus sur votre programme et de discuter des détails de la méthode de financement.

Je vous prie d'agréer, Docteur, mes sincères salutations.

Dr Howard Njoo
Vice-président, Direction générale de la prévention et du contrôle des maladies infectieuses

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From: Mcdougald, Catherine (HC/SC) on behalf of HPOC Communications / COPS (PHAC/ASPC)
Sent: 2021-02-04 2:18 PM
To: Njoo, Howard (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC)
Cc: Aung-Thin, Pamela (HC/SC); Baclic, Oliver (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Denis, Joel (PHAC/ASPC); Eckersley, Jennifer (HC/SC); Elmslie, Kim (PHAC/ASPC); Evans, Cindy (PHAC/ASPC); Gearey, Jennifer (HC/SC); Gorber, Timna (PHAC/ASPC); Hartigan, Maureen (HC/SC); HPOC Chief Operations / Chef COPS (PHAC/ASPC); HPOC EM / GU COPS (PHAC/ASPC); HPOC Communications / COPS (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Maidment, Leanne (PS/SP); McLeod, Robyn (PHAC/ASPC); Michel, Pascal (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Robinson, Kerry (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Russo, Laura (HC/SC); Salvadori, Marina (PHAC/ASPC)
Subject: [web posting] HEADS UP: Launch of Vaccine Injury Support Program (VISP) solicitation process
Attachments: Invitation to Submit an application_Web Content_SPPB - 2021-02-01_0947_EN.docx; Invitation to Submit an application_Web Content_ 2021-02-01_FINAL_FR.docx; PHAC_ML_VISP_2021-02-01_0947_FINAL EN.docx

---

Good afternoon Mr. Stewart, Dr. Tam, and Dr. Njoo,

*****Please note updated to posting date below*****

As per our established process for guidance and sensitive web content that may generate media interest, I am giving a heads up on the launch of Vaccine Injury Support Program solicitation process, which is planned for posting to Canada.ca next week.

Issue: On December 10, 2020, the Government of Canada announced that the Public Health Agency of Canada would create a Vaccine Injury Support Program (VISP). The program will provide financial support to people in the rare event that they experience a serious permanent injury after receiving a vaccine approved by Health Canada. On **February 8, 2021,** an open solicitation, along with targeted outreach to identified organizations will be launched to determine if there are any Canadian organizations interested and have the ability/capacity to deliver this program, while ensuring the selection is fair and transparent. There is concern that if the launch date is delayed, it will shorten the timeline for which applicants have to submit a proposal for a substantive program, as the deadline will remain the same (February 24). Shortening this window may deter applicants from applying.

We are planning to post on **Monday, February 8 , 2021**.

DOCUMENTS:
Invitation to Submit an Application – Web content (EN)
Invitations to Submit an Application – Web content (FR)

Media Lines : MLs – VISP – FINAL - EN

TIMING:
- **Monday, Feb 8, 2021**

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COMMS APPROACH:
• Reactive. Media lines have been prepared and are attached.

Please let us know if there are any concerns.

Thank you,
Katie

Katie McDougald

Health Portfolio Operations Centre (HPOC)
Pandemic Communications Response Team
Public Health Agency of Canada | Communications and Public Affairs Branch (CPAB)
catherine.mcdougald@canada.ca | 343-542-5803

Centre des opérations du portefeuille de la Santé (COPS)
Équipe de communication de l'intervention à la pandémie
Agence de la santé publique du Canada | Direction générale des communications et des affaires publiques
catherine.mcdougald@canada.ca | 343-542-5803

From: Mcdougald, Catherine (HC/SC) **On Behalf Of** HPOC Communications / COPS (PHAC/ASPC)
Sent: February 4, 2021 1:15 PM
To: Njoo, Howard (PHAC/ASPC) ; Stewart, Iain (PHAC/ASPC) ; Tam, Dr Theresa (PHAC/ASPC)
Cc: Aung-Thin, Pamela (HC/SC) ; Baclic, Oliver (PHAC/ASPC) ; Mcdougald, Catherine (HC/SC) ; Currie, Andrea (PHAC/ASPC) ; Denis, Joel (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; Elmslie, Kim (PHAC/ASPC) ; Evans, Cindy (PHAC/ASPC) ; Gearey, Jennifer (HC/SC) ; Gorber, Timna (PHAC/ASPC) ; Hartigan, Maureen (HC/SC) ; HPOC Chief Operations / Chef COPS (PHAC/ASPC) ; HPOC EM / GU COPS (PHAC/ASPC) ; Killen, Marita (PHAC/ASPC) ; Macey, Jeannette (PHAC/ASPC) ; Maidment, Leanne (HC/SC) ; McLeod, Robyn (PHAC/ASPC) ; Michel, Pascal (PHAC/ASPC) ; HPOC Communications / COPS (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Rendall, Jennifer (PHAC/ASPC) ; Robinson, Kerry (PHAC/ASPC) ; Romano, Anna (PHAC/ASPC) ; Russo, Laura (HC/SC) ; Salvadori, Marina (PHAC/ASPC)
Subject: [web posting] HEADS UP: Launch of Vaccine Injury Support Program (VISP) solicitation process

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We are planning to post on **Friday, Feb 5, 2021**.

DOCUMENTS:
Invitation to Submit an Application – Web content (EN)
Invitations to Submit an Application – Web content (FR)

Media Lines : MLs – VISP – FINAL - EN

TIMING:
• Friday, Feb 5, 2021

COMMS APPROACH:
• Reactive. Media lines have been prepared and are attached.

Please let us know if there are any concerns.

Thank you,
Katie

Katie McDougald

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Appel aux candidatures : Programme de soutien aux victimes d'une vaccination

Tous les vaccins administrés au Canada sont réglementés par Santé Canada et doivent répondre à des normes rigoureuses de sécurité, d'efficacité et de qualité pour que leur utilisation soit autorisée. Les vaccinations sont administrées par des professionnels de la santé qui suivent des protocoles établis. Par conséquent, les blessures graves et permanentes suite aux vaccins sont rares au Canada toutefois, comme pour tout produit médical, elles peuvent survenir.

Le 10 décembre 2020, le premier ministre Justin Trudeau a annoncé que l'Agence de la santé publique du Canada mettra en place un programme pancanadien de soutien aux victimes d'une vaccination sans égard à la faute.

Le programme de soutien aux victimes d'une vaccination garantira que les personnes au Canada qui subissent une blessure grave et permanente après avoir reçu un vaccin autorisé par Santé Canada ont accès à un soutien financier. S'inspirant du modèle qui est en place depuis plus de 30 ans au Québec, ce programme pancanadien garantira un accès juste et équitable au soutien pour toutes les personnes vaccinées au Canada.

L'Agence de la santé publique du Canada (ASPC) a le plaisir d'inviter les organismes admissibles à soumettre une demande pour la gestion du programme de soutien sans égard à la faute pour les personnes au Canada ayant subi une blessure grave et permanente suite à un vaccin.

Sur cette page

- Administrateur tiers
- Objectif et principaux éléments du programme
- Critères relatifs à l'expérience
- Processus de demande et renseignements requis
- Date limite pour la soumission

Administrateur tiers

Un administrateur tiers sera sélectionné pour gérer le programme de soutien aux victimes d'une vaccination au moyen d'un processus de demande de soumissions ouvert. Les organismes et sociétés canadiennes à but lucratif et sans but lucratif peuvent présenter une demande.

Le demandeur retenu travaillera de manière indépendante pour atteindre les objectifs du programme, en fonction des critères définis par l'Agence de la santé publique du Canada. L'Agence de la santé publique du Canada exige que

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l'administrateur tiers dispose d'expérience et d'expertise dans l'administration de programmes de soutien similaires. Le financement pour l'administration du programme et la gestion des paiements de soutien financier sera fourni à l'administrateur tiers en vertu d'une entente de contribution de cinq ans avec l'Agence de la santé publique du Canada.

Objectif et principaux éléments du programme

L'objectif du programme de soutien aux victimes d'une vaccination est de garantir que les personnes au Canada ont accès à un soutien financier au cas où elles subiraient une blessure grave et permanente après avoir reçu un vaccin autorisé par Santé Canada, administré au Canada. Voici les principaux éléments du programme :

Processus ouvert et transparent de réception des demandes – un système accessible au public pour la présentation des demandes d'indemnisation de blessures qui décrit clairement le processus et les critères d'admissibilité des demandeurs

Évaluation de la causalité – un processus qui détermine objectivement une relation causale probable entre la blessure et le vaccin et le degré et la durée de l'invalidité aux fins de l'établissement des paiements accordés

Administration des paiements de soutien financier aux bénéficiaires – paiements de soutien financier aux bénéficiaires basés sur un calendrier d'indemnisation qui s'aligne avec les pratiques industrielles acceptées pour l'indemnisation des blessures, et qui est conforme aux autres régimes d'indemnisation des secteurs public et privé. Le soutien financier comprendra le remplacement du revenu, les prestations de décès, le remboursement des coûts admissibles tels que les frais médicaux non couverts par ailleurs et les indemnités pour blessures.

Processus d'appel – un processus par lequel les demandeurs peuvent faire appel des décisions prises par la tierce partie, en ce qui concerne la causalité et le soutien financier.

Critères relatifs à l'expérience

L'organisme doit démontrer la façon dont il répond à chacun des critères suivants relatifs à l'expérience :

- décisions relatives aux demandes d'indemnisation en matière de santé (y compris un mécanisme d'appel);
- expérience dans l'évaluation de la causalité des blessures;
- gestion efficace de prestation rentable dans l'administration des paiements;
- gestion des renseignements personnels;
- prestation de programmes au niveau national disponible dans les deux langues officielles.

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Processus de demande et renseignements requis

Le gabarit de demande du programme de soutien aux victimes d'une vaccination de l'Agence de santé publique du Canada doit être utilisé pour soumettre une demande de financement. Pour obtenir une copie du gabarit de demande, veuillez écrire à phac.visp-psvv.aspc@canada.ca avec pour objet « Modèle de demande – Programme de soutien aux victimes d'une vaccination ».

En utilisant le gabarit, les demandeurs devront fournir les éléments suivants :

- aperçu de la manière dont l'organisme est en mesure d'entreprendre le programme proposé;
- description de la structure de gestion de l'organisme, de sa gouvernance et de sa capacité financière à mener à bien le programme;
- démonstration de la manière dont l'organisme répond à chacun des critères relatifs à l'expérience;
- renseignements détaillés sur la manière dont l'organisme est en mesure d'entreprendre chacun des éléments du programme;
- renseignements détaillés concernant les dépenses, les ressources et les processus nécessaires au programme.

D'autres lignes directrices seront incluses dans le modèle de présentation de la demande.

Les demandes seront soumises à un processus d'examen. Le demandeur retenu serra doté d'un financement pour administrer le programme de soutien aux victimes d'une vaccination.

Il est prévu qu'une entente de contribution de cinq ans soit signée avec le demandeur retenu. Cette période de cinq ans commencera à la date de signature de l'entente par les deux parties. L'entente initiale prendra fin cinq ans après sa signature, mais pourra être prolongée ou renouvelée, selon les besoins.

Les demandeurs dont la demande n'est pas admissible, est incomplète ou n'a pas été retenue en seront avisés.

Date limite pour la soumission

La date limite pour soumettre une demande est le 24 février 2021 à 23 h 59 HNP. Les demandes complètes doivent être envoyées à phac.visp-psvv.aspc@canada.ca.

Veuillez noter que l'Agence de la santé publique du Canada n'est nullement tenue de conclure un accord de financement sur la base de la présente invitation à soumettre une demande. L'Agence de la santé publique du Canada se réserve également le droit de rejeter ou d'accepter toute soumission, en tout ou en partie, ainsi que d'annuler ou de réémettre cette invitation à soumettre une demande à

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tout moment. En outre, l'Agence de la santé publique du Canada ne remboursera pas les frais engagés pour la préparation ou la présentation d'une demande.

La demande sera confirmée par courriel dans les deux jours ouvrables. Veuillez donc vous assurer que votre adresse courriel soit incluse. L'Agence de la santé publique du Canada vous informera par courriel de l'état d'avancement de votre demande dans les 10 jours ouvrables suivant la date limite de dépôt des demandes.

Pour obtenir des renseignements supplémentaires sur cette possibilité de financement, veuillez écrire à phac.visp-psvv.aspc@canada.ca.

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Call for Applications: Vaccine Injury Support Program

All vaccines used in Canada are regulated by Health Canada and must meet rigorous standards for safety, efficacy and quality before their use is authorized. Vaccinations are administered by trained professionals who follow established protocols. As a result, serious and permanent vaccine injuries are rare in Canada but, as with any medical product, they can occur.

On December 10, 2020, Prime Minister Justin Trudeau announced that the Public Health Agency of Canada will be implementing a pan-Canadian no-fault Vaccine Injury Support Program (VISP).

The VISP will ensure that people in Canada who experience a serious and permanent injury after receiving any Health Canada authorized vaccine have access to financial support. Building on the model that has been in place in Quebec for over 30 years, this pan-Canadian program will ensure fair and equitable access to support for all individuals immunized in Canada.

The Public Health Agency of Canada (PHAC) is pleased to invite eligible organizations to submit an application to administer a no-fault support program for people in Canada with a serious and permanent vaccine injury.

On this page

- Third-party administrator
- Purpose and main elements of the program
- Experience criteria
- Application process and information required
- Deadline for submission

Third-party administrator

A third-party administrator will be selected to administer the VISP via an open solicitation process. Canadian not-for-profit and for-profit organizations and corporations can apply.

The successful applicant will work independently to achieve the program's objectives, based on criteria outlined by the Public Health Agency of Canada. The Public Health Agency of Canada requires that the third-party administrator have experience and expertise in administering similar support programs. Funding to administer the program and manage financial support payments will be provided to the third-party administrator through a 5-year Contribution Agreement with the Public Health Agency of Canada.

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Purpose and main elements of the program

The purpose of the VISP is to ensure that people in Canada have access to financial support in the event that they experience a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada. Main program elements include:

Open and transparent claims intake process –a publicly accessible system for submission of injury claims that clearly outlines the process and eligibility criteria for applicants

Causality assessment –a process that objectively determines a probable causal relationship between injury and vaccine and the degree and duration of disability for the purposes of establishing payments

Administration of financial support payments to beneficiaries –financial support payments to beneficiaries based on a compensation schedule that aligns with accepted industry practices for injury compensation, and is consistent with other public and private sector compensation regimes. Financial support will include income replacement; death benefits; reimbursement of eligible costs such as otherwise uncovered medical expenses; and, injury indemnities.

Appeals process – a process by which applicants can appeal decisions made by the third party, with regards to causality and financial support.

Experience Criteria

The organization must demonstrate how it meets each of the following experience criteria:

- health claim adjudication (including an appeal mechanism);
- experience in injury causality assessments;
- cost-effective delivery in administering payments;
- managing personal information; and,
- providing program delivery at a national level in both official languages.

Application process and information required

The Public Health Agency of Canada's Vaccine Injury Support Program Application Template must be used to submit a funding application. To obtain a copy of the Application Template, please contact: phac.visp-psvv.aspc@canada.ca with the subject line "Application Template - Vaccine Injury Support Program".

Using the template, applicants will be required to provide the following:

- outline of how the organization is able to undertake the proposed program;

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- description of the organization's management structure, governance and financial capacity to carry out the program;
- demonstration of how the organization meets each of the experience criteria;
- detailed information regarding how the organization is able to undertake each of the program elements; and
- detailed information regarding expenses, resources and processes required for the program.

Further guidelines will be included within the template for the application submission.

Applications will undergo a review process. The successful applicant will be awarded funding to administer the VISP.

It is anticipated that a 5-year Contribution Agreement will be signed with the successful applicant. This 5-year period will begin on the date that the agreement is signed by both parties. The initial agreement will end five years after signing but may be extended or renewed, as appropriate.

Applicants with ineligible, incomplete or unsuccessful applications will be notified.

Deadline for submission

The deadline for submitting an Application is 11:59 p.m. PST on February 24, 2021. Complete applications must be submitted to phac.visp-psvv.aspc@canada.ca.

Please note, the Public Health Agency of Canada is under no obligation to enter into a funding agreement as a result of this invitation to submit an application. The Public Health Agency of Canada also reserves the right to reject or accept any submission in whole or in part, as well as cancel and/or re-issue this invitation to submit an application at any time. In addition, the Public Health Agency of Canada will not reimburse costs incurred in the preparation and/or submission of an application.

Application will be acknowledged by email within two business days, so please ensure your email address is included. The Public Health Agency of Canada will update you by email on the status of your submission within 10 business days following the due date of applications.

To obtain additional information about this funding opportunity, please contact phac.visp-psvv.aspc@canada.ca.

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Media Lines

Vaccine Injury Support Program

Issue: In early December 2020, the Public Health Agency of Canada (PHAC) announced that it would establish a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with provinces and territories. To identify a third party administrator for this program, PHAC is launching a solicitation process on February 5, that will run until February 24, 2021.

Upon Announcement – Key messages:

- As Canadians, we pride ourselves on our commitment to each other. By vaccinating, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories.
- Building on the model in place in Québec for more than 30 years, this will strengthen national immunization campaigns by ensuring fair and equitable access to support all individuals vaccinated in Canada.
- All immunization programs are based on the principle of reciprocity. As such, the Government of Canada is committed to ensuring that Canadians who support public health by being vaccinated are supported should they experience a serious permanent injury as a result of vaccination. This is extremely rare—less than one in a million.
- In the rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement—they deserve fair compensation.
- It also brings Canada in line with its G7 counterparts who all provide vaccine injury support for a minimum of mandatory vaccines, with most covering all recommended vaccines for vaccine preventable diseases.
- A third party is being sought to administer the program, and an open solicitation process is now underway.

If pressed on state of FPT discussions:
Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury support program (VISP), noting that Québec has had a vaccine injury support program since 1988, and will continue to administer its program provincially.

If pressed on timing:
The establishment of a vaccine injury support program has been previously identified as an area of importance by the Government of Canada, the provinces and the territories, to ensure that Canadians who support public health by being vaccinated are supported in the rare event they are injured.

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Questions and Answers:

Q1. What will a vaccine injury support program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories. Establishing a VISP will strengthen Canada's broader vaccine strategy and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national vaccine injury support programming in place.

The VISP will ensure that people in Canada who experience a serious permanent injury after receiving any Health Canada authorized vaccine have access to financial support. A suitable Third Party will administer the VISP; if no suitable third party is identified, the program would be federally run and administered by PHAC.

More details on the program and its administration will be available in the coming months.

Q2. Why is the Government of Canada considering using a third party to run the program?

The Government of Canada is seeking to select an experienced third party to administer the program through a contribution agreement. The suitable third party administrator will be able to apply its expertise in administering similar programs that require health claim adjudication and managing personal information as well as delivering a national program in both official languages. The third party will be able to quickly implement and deliver the program in a cost-effective manner.

Q3. Who will this solicitation be open to?

The solicitation is open to Canadian for-profit and not-for-profit organizations and corporations.

Q3. Does the Government of Canada continue to monitor a vaccine's safety after it is authorized?

Canada has a robust and well-established vaccine safety surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Vaccine manufacturers are required to continue to collect information about the long-term safety and effectiveness of their products. Pfizer BioNTech and Moderna, for example, will be following clinical trial participants for at least two years after receiving the second dose of the vaccine.

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Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

Q4. What if an adverse event following immunization is reported?

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g., muscle aches, bruising, mild headache) to very rare but serious adverse events (e.g., paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and efficacy of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

AEFI reports sent to PHAC from FPT jurisdictions are collated into the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Reports of serious adverse events are submitted to PHAC within 7 days of the receipt by the jurisdiction. FPT jurisdictions also notify PHAC of any reports of deaths within 24 hrs of becoming aware of the event. Reports of serious adverse events are processed within 1-2 days of submission and undergo medical case review within 1-3 days of data processing completion. If AEFI counts/rates exceed established background rates/thresholds based on international standards and what was observed during the clinical trials, a safety signal will be issued resulting in various actions. This could include Health Canada and the Public Health Agency of Canada warning Canadians about potential side effects, Health Canada suspending a lot or changing the recommended use of the product, or removing the product from the market.

Q5. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

The Government is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

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Canada has a robust and well-established vaccine surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

Health Canada will continue to review all the available safety data from ongoing clinical studies and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information.

Q6. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs to ensure they can be sold.

Q7. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing all COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available.

COVID-19 vaccine(s) are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

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Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q8. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases (VPD). Vaccine hesitancy can be attributed to factors related to confidence in vaccines (e.g. safety concerns), complacency (low perceived risk of VPDs), and convenience (difficulty accessing vaccines). The use of social media as an effective tool to spread misinformation and fear about vaccines also plays an important role in vaccine hesitancy.

Addressing vaccine hesitancy is a longstanding priority for the Public Health Agency of Canada (PHAC) but with the arrival of COVID-19, the stakes are higher than in the recent past. Concerted effort is underway with a range of partners to enhance education and guidance, address knowledge and research gaps, and improve coverage data. We are working with healthcare providers to meet the needs of frontline vaccinators and other health professionals who require tools to discuss vaccines with their patients and clients. We are also spearheading a national dialogue to meaningfully engage Canadians on about the importance of COVID-19 vaccines and vaccination more broadly.

This work builds on previous and existing efforts to improve vaccine coverage rates. For example, from 2017 to 2019, PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant as well as to debunk misinformation on vaccine safety and importance. A subsequent childhood vaccination campaign was launched (early 2021), with similar goals and objectives as well as serving as a reminder to parents to ensure children continue to stay up to date on their vaccination schedule. PHAC also leads an annual seasonal influenza immunization campaign targeting groups, such as seniors over 65 who are especially vulnerable.

PHAC is working with many partners to better understand and address vaccine hesitancy related to the new COVID-19 vaccines. These include both internal and external working groups with experts in vaccine hesitancy from different fields of study. This also includes a Vaccine Confidence Task Group made up of multidisciplinary advisors to help develop and provide the tools needed to meaningfully address vaccination questions and concerns. It also involves funding for stakeholders, provinces, territories, and community groups to help them develop tailored approaches that meet their community needs and speak in their community voices. Funding through the Immunization Partnership Fund will be leveraged to ensure Canada's diverse and often underserved groups are taking full advantage of the vaccines available to them.

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Canada

IMPLEMENTATION UPDATE: PAN-CANADIAN NO-FAULT VACCINE INJURY SUPPORT PROGRAM

January 20, 2021

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Purpose

- Provide an update on implementation of the pan-Canadian no-fault Vaccine Injury Support Program (VISP).

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Background

- [redacted]
- The Prime Minister announced the creation of the VISP following the First Ministers' Meeting on December 10, 2020
- The pan-Canadian VISP will build on the model in place in Québec for over 30 years.

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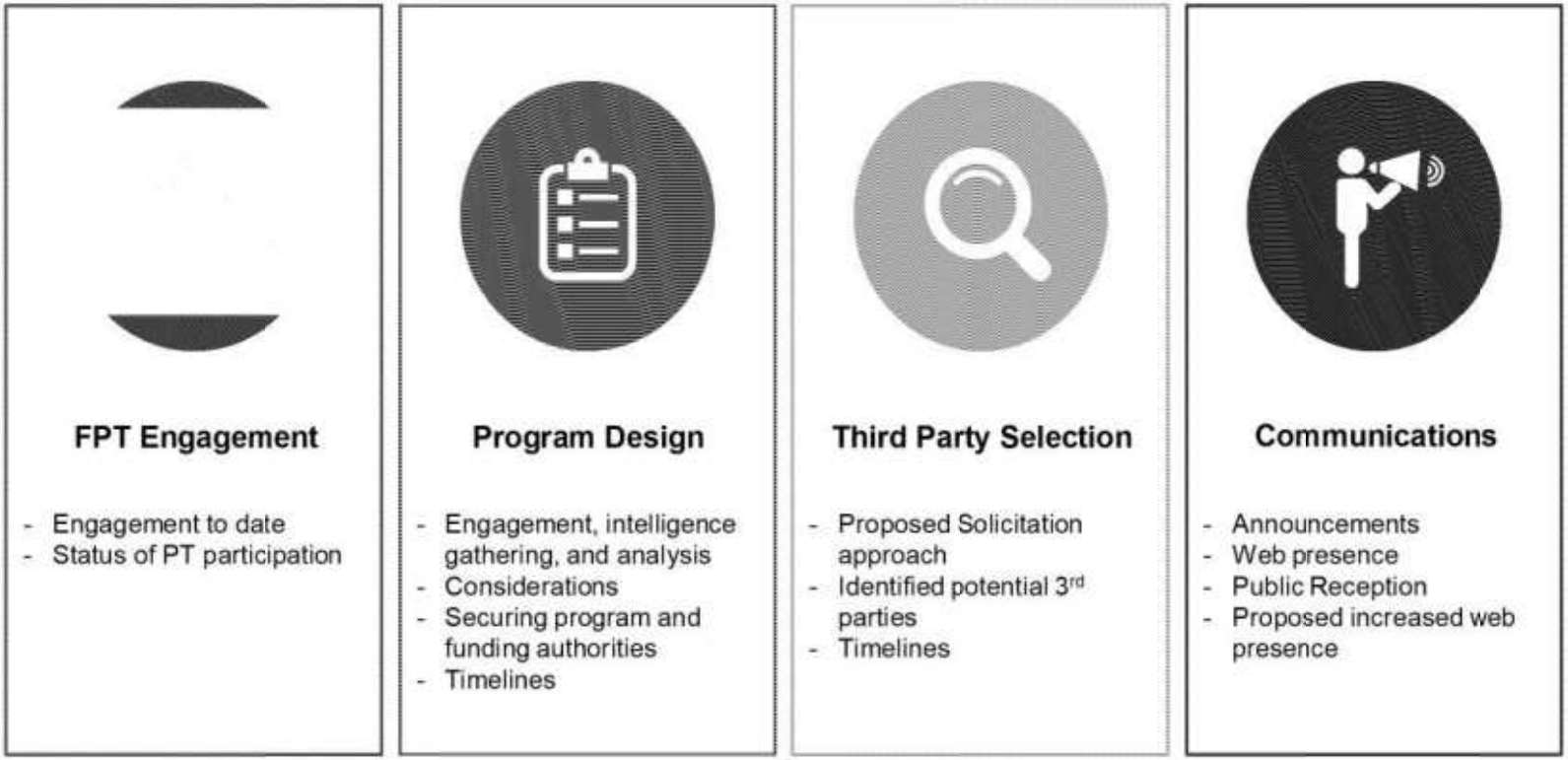
Four areas of work to implement the program…



FPT Engagement

- Engagement to date
- Status of PT participation

Program Design

- Engagement, intelligence gathering, and analysis
- Considerations
- Securing program and funding authorities
- Timelines

Third Party Selection

- Proposed Solicitation approach
- Identified potential 3rd parties
- Timelines

Communications

- Announcements
- Web presence
- Public Reception
- Proposed increased web presence

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FPT Engagement

- Presented at key FPT tables, including Special Advisory Committee (December 3, 2020), Conference of Deputy Ministers of Health (December 11, 2020), and Health Ministers' Meeting (December 17, 2020).

- Initial feedback from PTs has been fully supportive

- Request for formal "Opt-in / Opt-out" confirmation sent to PTs, with a return date of January 15, 2021. Responses to date (Jan 18):
  - Total number of PTs participating in pan-Canadian VISP: 8 (MB, NWT, NU, NS, BC, YK, NFLD, ON)
  - Total number of PTs opting out to establish/maintain their own equivalent program: 1 Qc

- Quebec signalled early on that it intends to maintain its current program with access to federal funding.

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Program Design (1 of 2)

- The intent is that the pan-Canadian VISP will align with Quebec's existing program as much as possible, in order to ensure equivalent programming across Canada.

- However, not all elements will be replicable at the national level. For example, QC uses their provincial automobile insurance program to calculate and administer payments to successful claimants.

- Discussions with officials from the *Ministère de la santé et des services sociaux du Québec* are underway to fully understand their program parameters (see annex), including engagement with the *Société de l'assurance automobile* to better understand QC's payment schedule/formula.

- Consultations have also taken place with federal departments to assess various approaches taken for other compensation programs:
  - VAC (compensation for service-related illness or injury); Public Safety (Memorial Grant Program for first responders), Health Canada (Thalidomide Survivors Support Program) and Indigenous Services Canada (Common Experience and Independent Assessment programs for residential school survivors).

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Program Design (2 of 2)

Many of the program design elements [redacted] However, some aspects require further development:

- **Support payment format**: QC's program provides three types of payments to victims: 1) lump sum for injury, 2) income replacement and 3) reimbursement of medical and related expenses. Financial implications are under review (i.e. longer term funding obligations for the GoC and the 3rd party administrator).
- **Causality assessments and determination of level of injury:** QC's program relies on a panel of 3 physicians to determine causality and injury
- **Determination of compensation:** A payment schedule for vaccine injuries will be required. QC's program uses their automobile insurance scheme – the pan-Canadian program should use an equivalent source.
- **Taxation and implications for other benefits**: Confirming tax-exemption status of payments, and assessing impact of payments on other compensation benefits (i.e. disability pensions).
- **Appeal process**: Identifying an appropriate body or approach for applicants to appeal 3rd party decisions.

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Program and spending authorities

[redacted]

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Third Party Administrator

- Solicitation approach based on balancing the need to rapidly determine if there are any Canadian organizations who are interested and have the ability/capacity to deliver this program, while ensuring the selection is fair and transparent.
- An open solicitation, along with targeted outreach to identified organizations (see appendix) will be launched in late early February.
- Expressions of interest will initially be sought, followed by full Invitations to Submit Funding Request (ISFR). Eligibility criteria will be specific. As such, we do not expect a large number of applicants.
- Eligibility criteria will include:
  - Experience in health claim adjudication (including an appeal mechanism)
  - Ability to deliver the program at a national level in both official languages
  - Experience in the management of personal information
- The Contribution Agreement with selected Third Party Administrator would be for 5 years followed by review.
- PHAC will administer the program, if there is no suitable third party identified.

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Communications

- VISP was announced by the PM on December 10, 2020 following the First Ministers' Meeting. A news release is accessible online.
- High level information regarding the VISP was added to the Vaccine safety page on the PHAC website on December 23, 2020.
- There is increasing interest by stakeholders and Canadians to have more information on the program design and eligibility.
- PHAC will develop a dedicated webpage for VISP. Approval will be sought to disclose additional program details such as:
  - Program design elements, including the solicitation for a 3rd party to delivery the program.
  - Further clarification on eligibility
  - The eligibility date of December 8, 2020 This will help in managing enquiries.
  - Deadline to apply for benefits (i.e. 3 years from vaccination with a HC-approved product administered in Canada.
  - Anticipated program launch date of June 2021.

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Next Steps/Key Dates

- Continue engagement with PTs (ongoing)
- Continue engagement with various stakeholders and experts to inform program parameters (ongoing)
- [redacted]
- Launch third party solicitation process (Feb 2021)
- [redacted]
- [redacted]
- Finalize contribution agreements (May 2021)
- Program launch expected by June 2021, with third party accepting claims for immunizations received as of December 8, 2020

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Annexes

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List of potential third party administrators*

Claims Administrators

[redacted]

Insurance Providers

[redacted]

Consulting/pension service provider

- Raymond Chabot Grant Thornton Consulting Inc.

[redacted]

Others

[redacted]

Third Parties Currently Administering Federal Programs

- Raymond Chabot Grant Thornton Consulting Inc. Public Safety Memorial Program
- Epiq Class Action Services Canada - Health Canada Thalidomide Survivors Support Program
- Epiq Class Action Services Canada - Indigenous Services Canada Independent Assessment Program
- Medavie Blue Cross - Administer various government-sponsored health programs on behalf of provincial and federal governments, including Veterans Affairs Canada and Immigration, Refugees and Citizenship Canada

**List compiled from Thalidomide process, engagement with OGDs, and others*

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Recap – VISP Drivers

Long-standing gap

- Establishing a national compensation program would leave a legacy of a strengthened immunization system in Canada.

Fairness and equity

- Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians.
- Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.

Securing supply

- As the only G-7 country without a national vaccine injury compensation program, Canada could be disadvantaged in vaccine procurement if some suppliers require this as a condition for accessing their product.
- Removes barriers to market entry for smaller manufacturers.

Leadership and responsibility

- Demonstrates that Canada, like other countries, recognizes that in the rare instances of serious harm due to vaccination, it is right that individuals receive compensation.

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Key Quebec Program Information

- Since its creation by legislation in 1988, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec

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19(1)
Subject to subsection (2), the head of a government institution shall refuse to disclose any record requested under this Act that contains personal information as defined in section 3 of the Privacy Act
Sous réserve du paragraphe (2), le responsable d'une institution fédérale est tenu de refuser la communication de documents contenant les renseignements personnels visés à l'article 3 de la Loi sur la protection des renseignements personnels

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Canada

SECRET

NO-FAULT VACCINE INJURY COMPENSATION IN CANADA

October 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- Create a pan-Canadian no-fault vaccine injury compensation (VIC) program to:
  - Ensure security of supply for COVID-19 vaccine
  - Ensure fairness of compensation for Canadians across the country
  - Fill gap in national immunization programming
- Discuss options and present a recommended approach

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Background

- In Canada, immunization is a shared Federal-provincial-territorial responsibility. There has been longstanding federal involvement in immunization activities and immunization safety through initiatives such as the National Immunization Strategy (2003).

- Immunization is a core component of public health measures and pivotal in reducing the incidence and severity of vaccine preventable diseases, at home and abroad.

- 26 countries have implemented a vaccine injury compensation program (e.g. US, UK, Germany, France, Japan, Italy, Nepal, Vietnam)
  - Canada is currently the only G7 country without a national VIC program.

- Quebec has a vaccine injury compensation program since 1988 and has spent $6.5M in compensation payments since its inception.

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Immunization Injury Compensation Program Drivers

Securing supply	• In unprecedented COVID-19 context, a national program would increase Canada's negotiating stature on international stage and influence to obtain supplies • Removes barriers to market entry for smaller manufacturers
Fairness for manufacturers and Canadians	• Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians. Courts have not historically awarded damages in vaccine injury claims.
Long-standing gap	• Repeated attempts since the 1980's to encourage P/Ts to implement program. Extending coverage to all vaccines would leave a legacy of a strengthened immunization system in Canada
Equitable coverage	• Protects Canadians and provides benefits in the event of a serious vaccine injury through universal and timely access to compensation, not just Quebec residents
Leadership and responsibility	• Protects Canadians as this is a new virus and new vaccine technologies are being deployed, in an environment of rapid testing and approvals

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Contributing to Broader COVID-19 Vaccine Roll-Out Strategy

COVID-19 Vaccine Roll-Out Strategy

1. Communicating and Engaging
   Building vaccine confidence
2. Securing and Selecting vaccines
   Obtaining the vaccine doses
3. Prioritizing vaccine recipients
   Establishing priority populations
4. Logistics and distribution
   Organizing logistics to deliver the vaccines on time and intact
5. Immunization and surveillance
   Immunizing Canadians (with provinces and territories)

VIC Alignment

1. Reassurance to Canadians they are protected in event of injury
2. Secure manufacturer/supplier participation in COVID-19 vaccine development and deployment in Canada
3. Mitigate risks to key populations posed by rapid development and new vaccine platforms
4. Build and maintain PT engagement and collaboration on vaccination in Canada
5. Strengthened surveillance to identify safety concerns

Governance

Cabinet Committee	FPT and Indigenous coordination	Expert advice and int'l engagement

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Considerations (1/2)

Supply

- While it is standard practice globally for governments to indemnify pandemic vaccine suppliers, no-fault VIC provides an additional level of supplier liability protection.

Fairness

- Coverage: Program is currently available only in Quebec. National program would allow equitable coverage across provinces.
- Insurance: Indemnification of suppliers is a contractual obligation and we currently pay manufacturers for liability protection by covering their legal costs. Canadians should receive the same protection.

Communications

- No evidence of impact on vaccine acceptance or uptake in jurisdictions with VIC. However, context is unique.
- Timing of public messaging, if at all, and potential impact on hesitancy will required careful planning.

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Considerations (2/2)

Provinces and Territories

- Significant FPT collaborative efforts from COVID-19 offer a window of opportunity. Currently limited capacity among PTs to negotiate implementation of PT-run programs

Operationalization

- Detailed program implementation and roll-out to be developped.

Budget

- Estimated cost: $23.7M million cost for five years (from 2021-22 to 2025-26), includes administration (intake, assessment, etc.) and payouts - federal government would pay all costs and fund Quebec's existing program

Rapid resolution

- VIC programs rapidly resolve injury claims whereas civil litigation is expensive, time consuming and unsuccessful
- VIC processes are more likely to be consistent both in the type of award and in the amount of compensation

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Option 1: Federally Funded Program, Administered by a Third Party

- Establish a pan-Canadian no-fault VIC program funded by the Government of Canada and administered by a Third Party (i.e. Canadian Blood Services), with the ability for P/T opt out to administer an equivalent program
- Contribution agreement with a review after five years
- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts
- Compensation for all uninsured costs resulting from an injury sustained following the administration of a National Advisory Committee on Immunization (NACI) -recommended vaccine administered within Canada
- Reduced flexibility for P/T opt out and risks of a potential agency relationship and complaints if viewed as a service contract

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Option 2: Federally Run Program within the Public Health Agency of Canada

- Establish a pan-Canadian no-fault VIC program run and entirely administered by PHAC, with the ability for P/T opt out to administer an equivalent program
- PHAC would take on all aspects of program administration including claims intake, assessments, all decisions, and payouts
- Some administrative services / causality assessments could be contracted out but final decisions and payouts remain with PHAC
- Compensation for all uninsured costs resulting from an injury sustained following the administration of a NACI-recommended vaccine administered within Canada

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Option 3: Vaccine Injury Compensation Tribunal

- Establish a pan-Canadian no-fault VIC program administered by a newly created third party tribunal, which would include scope for P/Ts to administer an equivalent program, with federal funding
- Established through OIC or legislation
- Tribunal would cover all aspects of programs administration, including claims intake, assessments, all decisions, and payouts
- Compensation for all uninsured costs resulting from an injury sustained following the administration of a NACI-recommended vaccine administered within Canada

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Recommendations

1) Federally Funded Program, Administered by a Third Party

- Establish a federally-funded pan-Canadian no-fault VIC program covering all National Advisory Committee on Immunization (NACI) recommended vaccines, to be administered by a Third Party and reviewed after five years.

2) Engage Provinces and Territories on a pan-Canadian program

- Engage P/Ts before program implementation to determine support and identify interests in independent P/T VIC programming, which would be supported with federal funding.

Messaging to be developed and tested to ensure a program

does not decrease intention to vaccinate, particularly among the "moveable middle"

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Key Milestones and Next Steps

- Extensive Central Agency engagement to ensure buy-in for critical path (immediately and ongoing)
- Exploratory engagement with provinces and territories as active partners in the VIC programming approach (early November)
- [redacted]
- [redacted]
- [redacted]
- Draft detailed implementation plan so that program can start accepting claims in June 2021 retroactive to individuals being immunized in January 2021 (November)
- Develop communications approach to outline VIC programming in context of Canada's COVID-19 immunization strategy (Winter 2021)
- FPT engagement on implementation (Winter 2021)

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Annex

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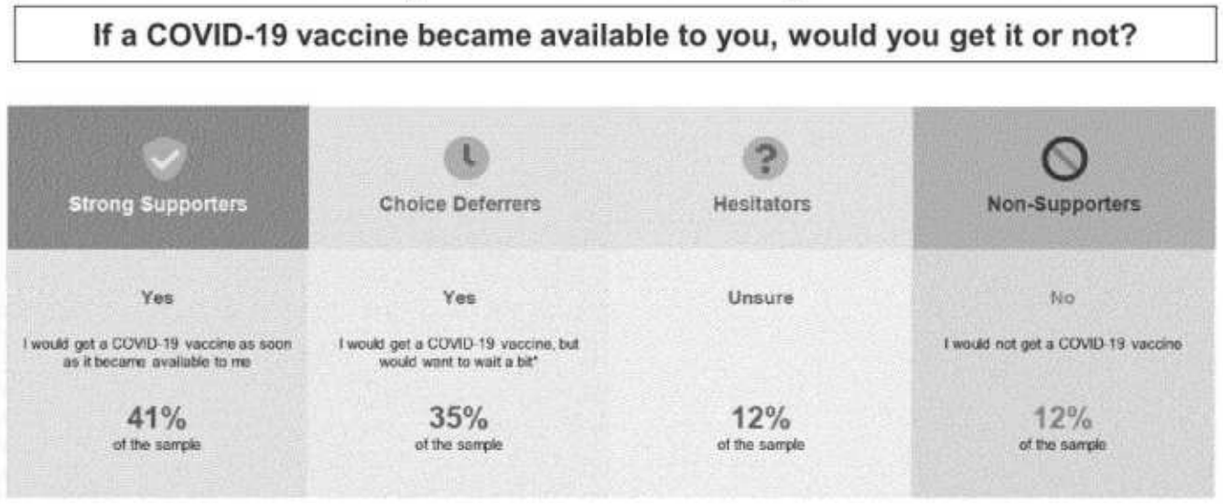
Impact of VIC on Intention to Vaccinate

- No evidence from international experience that VIC influences vaccine acceptance or uptake. No country has introduced a similar program during a pandemic.

- COVID-19 Vaccine Intentions Research conducted by PCO has identified confidence in Canada's vaccine testing and regulatory processes as a key factor influencing intention to vaccinate.*

  - In the research sample, a majority of **Strong Supporters** (86%) and **Non-Supporters** (74%) agree or strongly agree that their minds are made up about whether or not they will get a COVID-19 vaccine, suggesting that they may be much less influenced by our efforts.
  - Dissimilarly, just 37% of **Choice Deferrers** and only 3% of **Hesitators** agree or strongly agree that their minds are made up. These segments are the "moveable middle" and may be our best targets for public engagement and education.



- PHAC will work with PCO to determine the impact of a program on perceptions of vaccine safety and on intention to vaccinate (results available by end of October).

*Privy Council Office *Progress Update: COVID-19 Vaccine Intentions Research,* September 11, 2020

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Final Report

For: Update to "Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes"

Submitted to: Public Health Agency of Canada (PHAC)
Centre for Immunization and Respiratory Infectious Diseases (CIRID)

Submitted By: Dr. Jennifer Keelan, PhD, Taylor Rubens-Augustson, MPH, and Dr. Kumanan Wilson, MD, MSc, FRCPC

Date: August 21, 2020

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Executive Summary

Background

Universal vaccination programmes are a considered a cornerstone of public health and are responsible for the dramatic decline in the incidence and severity of many vaccine-preventable diseases. Overall, vaccines are required to undergo evaluations that determine their safety to the threshold of detection of the clinical trial (usually 1:10,000 risk). However, rarer serious adverse events following vaccination can and do occur, which at a population level, can become manifest. These events may not be detectable until vaccination has been used for many years in its target population. Even with years of experience with a particular vaccine technology, the precise aetiology of these rare events is often poorly understood and the possible or probable relationship between the adverse event and vaccination can remain uncertain. Injuries theoretically associated with a vaccine can also be caused by other factors, including exposure to circulating infectious agents, so it is rare that the causal association between a vaccine and any particular case of injury can be determined absolutely for any given case. Hence, adverse events following immunization (AEFI) are often referred to as inherently unavoidable: it is difficult to either predict who might have an adverse event that could lead to a serious injury or prevent the re-occurrence of these events in the future.

Rare adverse events remain a hazard of vaccination, but the individual and societal benefits of being immunized generally outweigh these rare risks. **Injured parties in Canada cannot successfully use civil litigation for risks inherent to vaccines and receive compensation for medical or rehabilitative costs, or lost income from a vaccine-related injury.** This means that every year in Canada, a few individuals will sustain serious harm and bear the burden of this harm while contributing to a public good. Internationally, there is a growing number of jurisdictions who have addressed this issue using a no-fault approach by creating a dedicated no-fault injury compensation programme to address vaccine-related injuries for all vaccines recommended by their governments or by including vaccine-injuries in existing pharmacological or treatment injury compensation insurance pools.

While the issue of reciprocity is a core objective of most vaccine-injury compensation programmes, it was manufacturer's liability (litigation related to adverse events) and threats of manufacturers' withdrawal from the market, or widespread concerns over vaccine safety, that galvanized the creation of most vaccine compensation programmes. Significantly, compensation programmes have been credited with contributing to a resurgence in investment in new vaccines in the United States and in maintaining the stability of vaccine production globally.

Additionally, both national, and WHO-led initiatives, have increased the surveillance capacity and sophistication of both international and national monitoring systems for vaccine-related injury. This has allowed for a rapid identification of possible injuries related to vaccines, such as in the identification of narcolepsy related to an adjuvant used in the 2009 European H1N1 vaccine programmes. Dr. Randy Mungwira, the lead researcher on a WHO member-state review of no-fault compensation programmes, attributed the creation of new vaccine-injury compensation

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schemes to a combination of the more sophisticated and coordinated AEFI surveillance systems and intensification of vaccine development and delivery globally (Mungwira et al., 2019).

In 2011, we wrote a report evaluating no-fault compensation programmes for vaccine-injuries (see Appendix). The purpose of the original report was to provide an in-depth analysis of several distinct types of no-fault programmes for vaccine-related injuries and to provide research-based recommendations for the design and implementation of a model programme in Canada.

The purpose of this report is to:

- update the key research findings;
- summarise relevant literature published since the writing of the original report;
- identify any new trends or concerns in the evolution of existing programs and the design features of any programs implemented or detected since our original reports were published;
- examine any discourse related to COVID-19 specific injury compensation.

Our Approach

This project was executed over a ten-day period. Key informants were contacted for interviews in all case-study jurisdictions. We used a snowball technique, beginning with our key informant list from our original project and key published sources. Upon contact, we asked informants to recommend any other contacts, and on interviewing these contacts, we made the same request and so forth. The response rate from researchers in the field was reasonable given the project's condensed timeframe and provided critical updates and context for our report. Data was collected primarily via email, telephone interviews, and a review of published literature focusing on the period from 2011onward. Some of the programme data was acquired through a review of publicly accessible government websites (U.S., Quebec). The primary source of information on the programmes from most jurisdictions was extracted from four key reviews of international programmes and from existing freedom of information requests (FOIR) made to the U.K. and New Zealand and available online. Data was analysed and compiled by the research team and used to update tables. Despite the availability of four key descriptive surveys of international no-fault compensation programmes, we encountered some challenges in extracting from secondary literature at the same granularity used for our original analysis. Where necessary, we made reasonable inferences based on the structure of the existing program and its history. For example, dissecting whether or not pandemic vaccines were included in some jurisdictions required us to look at how all biologics are typically handled, e.g., if all licenced vaccines are included in an injury scheme, we made the assumption that pandemic vaccines would also probably be covered.

Also, the list of recommended vaccinations and listed government funded vaccinations are not always wholly congruent. The twin objective of supporting universal immunization for some infectious diseases, and thus compensating any injured in that effort, is more complicated in an age when vaccines are being developed for a myriad of communicable diseases and cancer-causing viruses. While most no-fault programmes were implemented in a period where routine immunizations were aimed largely at children, more vaccine programmes are introduced each year that require adult or youth participation, such as the seasonal influenza vaccination. As

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national immunization schedules, recommendations, and programmes become more complex, international comparisons must increasingly rely on carefully extracted generalizations with reasonable exceptions to the rule. We have done something similar for this report. For instance, all schemes we analysed cover recommended childhood vaccines and adult seasonal influenza, so they are classified as covering childhood and adult recommended vaccines, but the caveat is that this is not true in all cases. Vaccines targeting adults, such as catch-up HPV programmes or shingles may or may not be included in the particular scheme.

However, from a review of the core components and design of no-fault programmes, we would argue that generalizations provide sufficient detail to capture the overall function and structure of international programmes. More detailed analysis would require in-depth case study analyses.

Key Findings

- There are four recent international reviews of no-fault compensation programmes, one of which was a comprehensive descriptive analysis of WHO-member state programmes (Keane et al., 2019; Kelly et al., 2011; Mungwira et al., 2019, 2020).
- From these reviews, we identified an additional 13 no-fault programmes.
- Canada is now the only G7 country without a no-fault vaccine injury compensation programme.
- We developed a broad schematic to describe no-fault compensation approaches: compensation programmes that deal exclusively with AEFI, and compensation programmes that subtend AEFI under a broader pharmacological or drug or treatment injury insurance scheme (DTI).
- The identification of new programs through a document review suggests that there are other currently un-identified programs that may be embedded in national disability or insurance schemes.
- Most new schemes identified are of the AEFI category.
- There have been no novel models for no-fault compensation programmes identified in recent scans; they largely fall under the same schematic developed by Evans (Evans, 1999) and further articulated in our 2011 report.
- No significant programme changes were noted for three of the four case studies in our original report; there have been several notable developments in the U.S. approach to vaccine-injuries associated with pandemic vaccines.
- Generally speaking, compensation programmes have had relatively stable claim rates and compensation levels. In jurisdictions with an absolute increase in claims and settlements, this has been attributed to a substantial expansion of seasonal influenza programmes and the 2009 H1N1 pandemic influenza campaign, e.g., the increase in compensation is reflected in the increased number of vaccinations.
- The U.S. Centers for Disease Control and Prevention (CDC) and leading scholars argue that the rates remain proportionate to the number of doses administered and meet both scientific and policy objectives of no-fault compensation (Meissner et al., 2019; Thompson et al., 2020).
- Spikes in petitions and, concomitantly, in compensation levels, can be seen in our case study data following the implementation of novel vaccines.

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- Spikes in petitions, but not necessarily in compensation levels, can also be seen following outbreaks of anxiety over a novel theory of harm associated with vaccines, as in the autism case.

No-fault compensation programmes and novel COVID-19 vaccines

- We anticipate that most no-fault programs will cover COVID-19 vaccines if they are government recommended and if the normal practice of adding newly recommended vaccines is followed, e.g., adding coronaviruses to statutory lists of included vaccine-preventable diseases, vaccine categories, or specific COVID-19 vaccines.
- COVID-19 vaccine development is occurring in a fairly unique global research environment with far more robust safety surveillance systems, with data sharing protocols and AEFI review capacity that can now quickly identify signals of harm and allow jurisdictions to react and change course if needed.
- Recent experiences in Europe, whereby one of the H1N1 vaccines utilised was associated with an increased risk of developing narcolepsy, created some public concern and stress for Nordic no-fault compensation programmes (there were reports of delays in reviewing petitions and dissatisfaction with compensation rates). However, the compensation schemes appear to have functioned as designed: it appears from media reports those who developed narcolepsy in the window period following immunization were compensated.
- Countries with existing programmes may review the experience with the European H1N1 vaccine – narcolepsy settlements with the intent to proactively bolster base funding rates or rate the risk higher for insurance schemes in anticipation of COVID-19 adverse events.
- Researchers have already identified possible adverse events associated with Middle East Respiratory Syndrome (MERS) from laboratory studies (e.g., antibody mediated disease enhancement), but the pandemic H1N1 experience suggests that the possibility exists for there to be completely unanticipated adverse events in any pandemic vaccine deployment.
- The U.S. has developed an alternate approach to dealing with pandemic vaccines that may be adopted by governments with no-fault compensation programmes. The U.S. Countermeasures Injury Compensation Program (**CICP**) was created to delineate claims made from a novel vaccine from the routine vaccinations covered by their Vaccine Injury Compensation Program (VICP).
- The U.S. **CICP** delivers a blanket immunity against liability for the H1N1 vaccine, whereas under the VICP scheme, claimants could conceivably choose to pursue a claim after receiving and rejecting a VICP award.
- The U.S. model uses emergency/pandemic legislation to wall-off medical treatments developed and deployed in a pandemic from any exposure to liability for injuries or harm caused by defects in manufacturing or accelerated drug review processes.
- No-fault programmes should anticipate a spike in claims and compensation following the implementation of a COVID-19 vaccine. However, history suggests that many of the early adverse events associated with the novel vaccine will be eventually excluded if data is amassed through an annual vaccine programme or if the vaccine is added to a routine childhood schedule.

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Summary of Findings

- No-fault compensation programmes have proved to be a long term policy solution to redress vaccine-related injuries; longstanding programmes in multiple jurisdictions attest to their effectiveness; findings of international surveys support the assertion that no-fault programmes endure because of the core need for reciprocity to redress injuries sustained while participating in vaccination programmes; they also serve a critical role in protecting manufacturers from liability against unanticipated or unavoidable harms arising from routine vaccination, and in doing so protect the vaccine supply and stimulate vaccine innovation.
- There is no evidence that systems that covered the H1N1 pandemic vaccine were inadequately funded or unable to manage the increased uncertainty posed by a novel vaccine.
- The COVID-19 pandemic will uniquely challenge governments with existing no-fault programmes because it is both a novel vaccine category and a novel vaccine-preventable infectious disease. Furthermore, the speed of vaccine development is unprecedented.
- There is a high likelihood of unanticipated adverse events associated with a COVID-19 vaccine and countries with existing no-fault compensation programmes will be better prepared to address these injuries.

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Update of international review of no-fault compensation programmes and review of new systems identified

Summary of updates to existing programmes and new systems identified

There appears to be a growing interest worldwide in implementing no-fault vaccine injury compensation programmes, with a steady increase in number since our 2011 report. We have identified 13 additional programmes in the literature not addressed in our 2011 report, including eight in the European region (Austria, Finland, Hungary, Iceland, Latvia, Luxembourg, Russia, Slovenia), three in the Western Pacific region (China, Republic of Korea, Vietnam), and two in the South-East Asia region (Nepal, Thailand) – see Table 1. The core of existing programmes identified in our 2011 report appear to remain relatively stable, with only minor changes related programme administration and updates as more clarity regarding types of compensation offered to claimants has become available (see Table 2). In the following section we summarize the methods used to update new and existing programmes, analyze key findings (organized by programme element), and discuss approaches to compensation for adverse events following pandemic vaccination (Table 3).

Methods

We identified four key reviews (Keane et al., 2019; Kelly et al., 2011; Mungwira et al., 2019, 2020) which provided both a general overview of existing programmes and how vaccine-injury compensation programmes have evolved over the past decade since our 2011 report (see Table 4). In general, reviews examined no-fault compensation schemes in relation to the following programme elements: administration and funding, eligibility (e.g. vaccines covered, timelines, types of injuries compensated, citizenship requirements), process and decision-making, standard of proof, elements of compensation, and litigation rights. These reviews form the basis by which we used to update existing programmes and identify new programmes.

Table 4: Key reviews on no-fault vaccine injury compensation programmes globally published since our 2011 report.

Review	Description
Mungwira et al. (2020)	Scoping review and survey of WHO member states (MS) with no-fault VICP. 25 MS identified to have a VICP; 23 programmes described (including two from Japan).
Mungwira et al. (2019)	Descriptive analysis of the economic and vaccine safety surveillance characteristics of WHO MS implementing VICPs.
Keane et al. (2019)	Integrative review of international literature of no-fault vaccine injury compensation programmes (internal report commissioned by the government of Ireland).
Looker & Kelly (2011)	Review of no-fault compensation programmes for adverse events following immunization. 19 jurisdictions included.

References in the above reviews were also scanned to trace any other potentially relevant sources that would help investigate and triangulate updates to existing programmes and glean additional information on programmes not included in our 2011 review. Additionally, we

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performed a scan of literature on no-fault vaccine injury compensation programs more broadly and those related to the H1N1 pandemic vaccine using the University of Toronto and University of Ottawa's library database and Google Scholar. Where available, we also reviewed government websites, legislation documents, case law, and policy literature (when English documents were not available, Google translate was used to interpret information). Furthermore, a snowball sampling strategy was used to identify potential key informants (e.g. academics, immunization experts, etc.), who we contacted via phone and email to gain further insight on the current status of no-fault vaccine injury compensation programmes and inquire about the possibility to access unpublished programme data. Of those who were available, informal interviews were conducted via phone and video conferencing.

Overview

Overall, there has been a steady increase in the number of vaccine injury compensation programmes over the last decade. We identified 13 additional jurisdictions from our last report; however, it is very likely that there are other programmes not captured in the literature as they may be less visible when administered as part of a broader medicine injury compensation programme. We also learned from key informant interviews that ad-hoc programmes are being implemented in parts of Africa and South America, specifically in the Ivory Coast and Brazil. The majority of programmes identified are in high-income countries, but more recently, low and lower-middle income countries have begun to adopt no-fault vaccine injury compensation programmes, including Nepal and Vietnam.

Administration and Funding

Given that vaccine injuries are relatively rare and require national-level expertise for identification, evaluation, causality assessment and surveillance, nearly all programmes are administered and at the national/federal/central level of government and funded through general revenues. This is with the exception of Germany, Italy, and Quebec, which are administered at the provincial level, and China, which is administered and funded by multiple levels of government. Japan is also funded by multiple levels of government. Switzerland had previously administered their programme at the cantonal level; however, this was amended in 2016 to be executed by the central government.

The majority of the Nordic countries adopt a different approach to programme administration and funding and are housed within a broader drug and treatment injury compensation programme. In Finland and Sweden, programmes are administered by private drug insurance and funded by contributions from pharmaceutical companies using a manufacturers' levy. Norway operates under a combined system where it is administered by the central government but funded via a combination of national treasury funds and contributions from the pharmaceutical industry. New Zealand's programme is administered as part of a broader no-fault accident compensation programme (Accident Compensation Corporation) and funded by specific tax revenue, including taxes on employers and wage earners, vehicle licensing and government investment income.

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Furthermore, in China, Korea and Japan, the administration and funding of programmes depends on whether the vaccines in question are under the National Immunization Programme (NIP) or not. Compensation for vaccine injuries related to NIP vaccines are administered and funded by the central government, and non-NIP vaccines are handled by the pharmaceutical industry. In the U.S. and Taiwan, excise taxes on every dose of vaccine administered are used to fund their no-fault vaccine injury programmes.

Eligibility

Vaccines covered

The majority of programmes offer compensation for vaccine-related injuries for government recommended vaccines for both adults and children. In countries where vaccine compensation falls under a broader pharmacological adverse events/injury compensation insurance, all registered vaccines are covered because they fall into the category of regulated pharmaceuticals (general insurance scheme). In these countries, any vaccine, including vaccines during pandemics, are covered by default of their registration. In certain jurisdictions, compensation is awarded only for those which are mandatory or required (Slovenia, Hungary, France, Taiwan, Italy and Japan – NIP vaccines). In the U.K., Quebec and the U.S., vaccines eligible for compensation include those recommended by the government and listed in the legislation.

Eligible compensation

All jurisdictions have a threshold of injury in order to be eligible for compensation, with some countries having a higher threshold than others. For example, in the U.K., only vaccine related injuries resulting in greater than 60% permanent disability are eligible for compensation. In other jurisdictions, compensation is considered above a minimum monetary amount of damages/loss (e.g. Denmark, Norway, Korea).

Types of compensation

At minimum, most programmes compensate for medical costs, disability pension, non-economic loss and death benefits. Certain jurisdictions award lump sum payments (e.g. U.K., Switzerland). Remaining jurisdictions are split on whether they base compensation using a standardized process or on a case by case basis.

Coverage of pandemic vaccines

We reviewed published and unpublished literature to identify structural components of vaccine injury compensation programmes (See Table 3). In jurisdictions operating standalone no-fault compensation programmes (e.g. specific to vaccination), this was categorized at "AEFI" – adverse events following immunization. Jurisdictions operating under a broader pharmacological and treatment injury compensation programme were categorized as "DTI" – drug treatment injuries. We determined whether or not pandemic vaccines would be included in each jurisdictions' programme based on which vaccines are covered in each jurisdiction and whether or not, to the best of our knowledge, the existing programme automatically adds any newly licensed or registered biological product to their compensation programme or if there is a separate process by which new and pandemic vaccines are eligible for compensation following

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an AEFI (e.g. expert review, etc.). We also based this provisional finding on any information regarding how the jurisdiction treated pandemic vaccines in the past, for example the H1N1 vaccine. This was the case for the U.K., who only covers vaccines listed in the legislature, and the U.S., who has a separate programme for pandemic vaccines. Jurisdictions with a DTI programme structure are likely (probable) to include pandemic vaccines as all licensed products are automatically included in these schemes (e.g. Nordic countries, New Zealand). This informed our predictions of whether or not a COVID-19 vaccine would be included in a no-fault vaccine injury compensation programme.

In jurisdictions with a drug treatment and injury compensation approach (e.g. the Nordic counties, Latvia, New Zealand), we determined that pandemic vaccines are very likely ("probable") to be covered under the programme as there are currently no vaccines that are barred from compensation. This also led us to predict that the likelihood of covering an eventual COVID-19 vaccine is also probable. We are cautious to report in absolute terms as experiences from the H1N1 and adverse events related to the vaccine may influence the decision to include a novel coronavirus vaccine.

In jurisdictions with programmes specifically addressing injuries related to adverse events following immunization, we note that the likelihood of covering pandemic vaccines and a COVID-19 vaccine is probable if conditions are met (e.g. if the COVID-19 or any other pandemic vaccine is included as a government-recommended vaccine, it is probable it will be covered). An outlier to these programmes is the U.K., who excluded the H1N1 vaccine from their list of vaccines eligible for compensation, and therefore we predict that it is very unlikely the COVID-19 vaccine would be covered.

Finally, the U.S. is one case in which we can say with certainty that pandemic vaccines are covered and treated separately under the CICP, as was seen with the H1N1 vaccine. An eventual COVID-19 vaccine will fall under and be covered by this programme.

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Case Study Updates

An in-depth description and analysis of no-fault compensation in the U.S., U.K., New Zealand and Quebec can be found in our original report. Updated statistics were acquired through government websites (U.S. - see Table 5; Quebec - see Table 6a and 6b), through existing FOIRs and research reports found through our literature scan (New Zealand - see Tables 7a and 7b), U.S. CICP, U.K. - see Tables 8a and 8b) (Accident Compensation Corporation, 2020; Department of Health and Social Care, 2019; Roos, 2011). Since 2010, no-fault programmes in the U.K., New Zealand and Quebec have not changed in a substantive way, although changes to the manner in which data is now aggregated for years before 2000 in Quebec, and reported improvements to accessing New Zealand's programme, have made comparisons to our 2011 analyses more complex. In brief, the reported increases in the number of claims and rates of compensation in the summary table (Table 9) are partially due to how data is aggregated (Quebec) or improvements to the claims process (New Zealand). In addition, all jurisdictions showing increases in both claims and settlements attribute the bulk of the increase to seasonal influenza vaccine and/or H1N1 pandemic programmes**. In other words, there has been a significant expansion in the number of vaccines given and this is now reflected in the injury claim data.**

An analysis of compensation rates to doses of vaccines administered in the U.S. supports this assertion (Health Resources and Services Administration (HRSA), 2020; Meissner et al., 2019; Thompson et al., 2020). A more useful analysis, moving forward, would be to use this approach to measure cases and compensation per dose administered. Regrettably, this data is notoriously difficult to tabulate, and it was beyond the scope and timeframe of this project to do so. Updated statistics for the U.S., Quebec, New Zealand and the U.K. vaccine injury programmes are summarised in Table 5 (U.S.), Tables 6a and 6b (Quebec), Tables 7a and 7b (New Zealand) and Tables 8a and 8b (U.K.). An updated summary table (Table 9) of all case studies reiterates that, with the exception of New Zealand, claim rates have remained proportionate to the objectives of the programmes and rare risks of adverse events.

Overall, the number of claims and compensation paid out has remained relatively stable. Over the past ten years, for example, the U.K. had less than 120 claims per year with a settlement rate that varied between 0-4% of claims. In the U.S. VICP, 22,106 petitions were filed; 19,114 petitions were adjudicated and 7,477 (39%) were compensated. In Quebec, over the same period, there were between 0 and 27 claims adjudicated with 0-6 claims paid out in a single year (totaling 28 injury settlements in the ten-year period). Seasonal influenza represents the largest number of petitions and claims settled in the U.S. and New Zealand and also led to an uptick in petitions in Quebec. Similar data showing which vaccines were associated with reported claims was not available for the U.K.

In the U.S., there has been a steady climb in the percentage of cases compensated from a near historic low of 20% in 2004 to rates surpassing 70% between 2015-19. Additionally, claims filed have regularly breached 1,000 per annum in the past five years. The increase in both absolute claims and compensation rates can be attributed to two factors. First, in an analysis of the VICP by Dr. James Hamblin and published in the Atlantic in 2019, he argued that it was public criticism that spurred changes in the administration of the U.S. VICP and its vaccine court. A 2015 article by Stanford Law professor Nora Engstrom had argued the VICP was failing to provide more rapid resolution to injury cases than the tort system would and, more pointedly, failing the spirit of "generosity" spelled out in the Vaccine Injuries Compensation Act. Under more scrutiny

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regarding the efficiency and fairness of the claims process, the VICP began to rapidly settle claims where the balance of probabilities was uncertain or under-determined by evidence. In doing so it significantly increased the number of concessions—settling cases in an administrative manner without indicating a judgment of causation. In the period 2006-18, 70% of VICP were concessions rather than arbitrated judgements (HRSA, 2020).

The second factor was a significant increase in cases related to seasonal influenza vaccine, in particular, claims made related to serious shoulder injuries (shoulder Injuries following immunization, SIFR) (Hesse et al., 2020) and fainting episodes that, in a small percentage of cases led to ancillary harm from falls or suddenly losing consciousness (e.g., while driving) (Hamblin, 2019). The number of claims related to seasonal flu began to dominate the U.S. VICP, which has, somewhat recursively, led to an information campaign and advertising by lawyers specialising in vaccine injury compensation, thus increasing public awareness of these types of injuries and leading to even more claims filed. As a consequence, the proportion of claimants compensated has markedly shifted away from injuries related to routine childhood immunizations to adults who experienced adverse events associated with the seasonal influenza vaccine. In a Health Resources and Services Administration (HRSA) Data and Statistics report on vaccine injury compensation, they reported that between 2006, when flu vaccine was added to the compensation programme, and 2018, there were 6,368 claims filed related to seasonal influenza (188 related to a death and 6,180 related to injury). A total of 3,672 received compensation and 633 have been dismissed 2,062 remaining (HRSA, 2020).

The number of successful shoulder injury compensation claims (SIRV), especially since 2010, has sparked research into their causes and the resulting literature has identified issues in vaccination techniques related to these injuries. The report by Hesse et al. (2019) specifically outlines new training recommendations for those administering vaccines: pharmacists (the largest share of claims), nurses, and physicians. This evolving process substantiates claims that vaccine injury compensation programmes can actually identify problems and assist in improving vaccine safety.

More recently, after an exhaustive review of the literature, the U.S. VICP has moved to remove both shoulder injuries and vasovagal syncope (vaccine-associated fainting) from the Table of Injuries reflecting the more robust epidemiological data that identifies these injuries as arising from *avoidable* rather than *unavoidable* harm. These injuries should be preventable with adequate training and education of health care providers (Health Resources and Services Administration (HRSA) and Department of Health (HHS), 2020)

Two recent published reviews by Meissner et al. (2019) and Thompson et al. (2019) further support our conclusions that programme objectives are largely being met in the U.S. The total number of doses of flu vaccine administered is quoted as being "1,672,400,000: with 893 cases falling under compensable concession; compensable court decision 202 and compensable settlement 2,528; 633 dismissed" (HRSA, 2020). In the most recent updated data set reported by the U.S. federal health department (HRSA), they further quote the U.S. CDC who summarised that the compensation per dose delivered meets both scientific expectations and programmatic objectives:

> *"...from 2006 to 2018 over 3.7 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 7,370 petitions were adjudicated by the Court, and of those 5,151 were compensated.*

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This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated."

(HRSA, 2020)

Despite the increase in claims and settlements for influenza-related injuries due to, what is now regarded as avoidable injuries, it can be argued that the U.S. no-fault programme functioned precisely as it was intended. It compensated cases until the epidemiological evidence supported ruling out the kinds of harm claimed by petitioners and simultaneously alerted the research and the medical community to a problem in administering vaccines.

US Countermeasures Injury Compensation Programme (CICP)

In the US, The Public Readiness and Emergency Preparedness Act (PREP Act) authorized the establishment of the CICP. The U.S. CICP was created in 2005 to ensure that actions taken by government, health care workers and industry partners in response to a national emergency or security threat were given a blanket immunity against liability for injuries or negligence. Whereas under the VICP scheme, claimants could conceivably choose to pursue a claim after receiving and rejecting a VICP award, the CICP provides comprehensive statutory indemnification.

The CICP was updated during the 2009 H1N1 pandemic to cover vaccines, antivirals and medical devices utilised during the pandemic. Petitioners to the CICP submit an application which undergoes an administrative review and evaluation. Significantly, unlike the VICP claim process, claimants do not utilise legal representation. The claims adjudication is performed by an expert panel who in turn can use a Table of Injuries to rapidly adjudicate claims or an expert case review.

Benefits available under the CICP include: costs for drugs and medical treatment, wage replacement, and survivor death benefits (The Law Library, 2018). While there are no published reviews or data available related to H1N1 compensation under the CICP, the former Director of the VICP, Dr. Vito Caserta was quoted in an article published by the Centre for Research in Infectious Disease Research and Policy: "To date, 54 claims have been filed that appear to have been submitted with sufficient medical records to place them in line for review. Of these, 26 have begun a medical review" (Roos, 2011).

The core function of the CICP has been met in that is has provided blanket immunity from any litigation for the H1N1 vaccine programme and the CICP has been updated to include countermeasures related COVID-19 vaccines.

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Discussion

Since the completion of our report, the weight of evidence we reviewed supports the assertion that no-fault compensation programmes continue to meet their core objectives: to maintain public support in universal immunization programmes, provide compensation for injuries, and through liability protection, maintain and protect the supply of vaccines.

Two additional converging factors have emerged which may be significant in governments' retaining their no-fault compensation programmes and in the growth of compensation schemes globally. First, there is a consensus that emerging-infectious diseases (EID) linked to various factors such as increased global travel and mobility, and intensification of higher risk forms of agriculture in developing countries, will increase the risk of more frequent pandemics and the need for an aggressive vaccine development strategy. There has been a significant expansion in vaccine programmes globally and this has resulted in concomitant increases in reported injury claims.

Second, accelerated testing of vaccines to effectively intervene during a pandemic exposes manufacturers to a degree of uncertainty and risk that cannot be shouldered by even the most established vaccine innovators and manufacturers. These factors will increase the pressure on governments to develop and effective strategy to deal with the rare but inevitable adverse events associated with vaccination.

Protecting manufacturers and health agencies from litigation related to injuries linked to novel vaccines released during a pandemic has become routine. However, it appears that immunity against product liability is an inadequate remedy for vaccine injuries which have the potential to create widespread public concerns. Vaccine manufacturers are at high risk for bearing the brunt of public concerns about vaccine injuries. The lack of a rapid, fair and accessible compensation scheme for vaccine-related injuries has the potential to seed and bolster the already robust anti-vaccination movement.

Jurisdictions that lack a comprehensive vaccine compensation program can look to a model where ad-hoc inclusion of vaccines into existing emergency-response programmes provided a similar kind of insurance against injuries while protecting providers and manufacturers of medical products and services. In recent discussions over the development and dissemination of novel COVID-19 vaccines, the WHO has proposed integrating injury-compensation schemes into WHO-led vaccine initiatives. However, the WHO is also actively engaged in promoting and supporting member-states' initiatives to create programmes of their own (personal communication with WHO researcher, 2020).

The model of using an emergency program to insure against injuries sustained by a pandemic vaccine, versus integrating pandemic vaccines into a broader compensation scheme, has some advantages. It can justify providing more comprehensive immunity against liability and reflects the challenges faced by governments and manufacturers who are tasked with rapidly releasing a new vaccine after an accelerated review process.

However, the justification to provide compensation for injuries sustained from vaccines related to a pandemic but not for injuries sustained in the ongoing efforts by all citizens to maintain herd immunity against infectious diseases will likely fail to satisfy large segments of the population. A

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stand-alone emergency vaccine-injury compensation programme only makes sense if there is already a programme to cover routine immunizations. Support for ongoing immunization programmes is critical and an ad hoc approach to compensation of adverse events would only highlights this gap in Canadian immunization policy.

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Acknowledgements

The research team would like to thank the following researchers and scientists for assisting us with our research: Dr. Sam Halabi, Dr. Randy Mungwira, and Dr. Natasha Crowcroft.

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Appendix

Table 1: Summary of additional jurisdictions identified with no-fault vaccine injury compensation programs since our 2011 report*

Jurisdiction	Austria	Latvia	Nepal	Vietnam	Slovenia	Hungary
Year	1973	2014	2018	2016	1997	2005
Administration	Ministry of Social Affairs, Health, Care and Consumer Protection	National Health Service	Ministry of Health	Department of Health Records	Central government	Central government
Vaccines covered	All licensed vaccines	All vaccines	Gov. recommended vaccines	Gov. recommended vaccines in National Immunization Programme (NIP)	Mandatory or vaccines pro-actively recommended by law	Mandatory or vaccines pro-actively recommended by law
Eligible comp. (e.g. unexpected injury, disability or death, etc.)	Severe bodily harm	Damage to life or health (including moral damage); treatment-related expenses	Physical losses (e.g. mutilation, death)	Disability or death	No data	No data
Types of comp. (e.g. medical costs, funeral, disability pension, death benefits, lost wages, etc.)	Medical costs, disability pension, non-economic loss, death and disability benefits; rehabilitative costs; lump-sum payments for less severe injuries	Maximum compensation of EUR 142,290 for damage to health or life; medical costs up to EUR 28,460	Does not specify	In cases of disability, equivalent to 30 months base salary or calculated based on lost/reduced income with standardized formula; expenses prior to death; funeral expenses; mental suffering for relatives; earning loss	Medical, disability pension, funeral costs	Medical, disability pension, funeral costs
Funding	Government funded	Treatment Risk Fund, funded by contributions from medical institutions	Government funded	Government funded	Not specified, but likely government funded	Not specified, but likely government funded

Jurisdiction	Luxembourg	China	Finland	Rep. of Korea	Iceland
Year	2000	2006	1983	1995	2001

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Admin	Ministry of Health	All levels of government	Private drug insurance	Korea Advisory Committee on Vaccine Injury Compensation	Icelandic Health Insurance (IHI)
Vaccines covered	Gov. recommended vaccines	Gov. recommended vaccines	All vaccines	Gov. recommended vaccines in NIP	Not available
Eligible comp. (e.g. unexpected injury, disability or death, etc.)	No data	Severe disability or death directly attributable to vaccine	Loss of functional ability for at least 14 days	Moderate to severe adverse events (any vaccine injury where treatment cost more than 300,000 Korean won)	Not available
Types of comp. (e.g. medical costs, funeral, disability pension, death benefits, lost wages, etc.)	No data	Province-dependent	Unreimbursed medical costs, disability pension, noneconomic loss, death benefits, pain and suffering, additional losses arising from injury less statutory benefits	Not available.	Not available
Funding	Not specified, but likely government funded	Government funded for NIP vaccines; non-NIP vaccines funded by pharmaceutical industry	Drug manufacturers', distributers' and suppliers' tax	Government funded for NIP vaccines; non-NIP vaccines funded by pharmaceutical industry	Not available

Note: no data was found on Russia or Thailand.

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Table 2: Update and summary of existing jurisdictions with no-fault vaccine injury compensation programmes included in our 2011 report

Jurisdiction	Germany	France	Japan[1]	Switzerland	Denmark	New Zealand	Sweden
Year	1961	1964	1970	1970	1972	2005	1978
Administration	State (pension system) under federal regulation	Ministry of Health & Solidarity	Ministry of Health, Labour and Welfare	Federal Department of Home Affairs	Danish Patient Compensation Association	Accident Compensation Corp. (Crown Corp.)	Private Drug Insurance
Vaccines covered	Gov. recommended vaccines	Mandatory vaccines	Gov. recommended vaccines	Gov. recommended vaccines	All vaccines	All vaccines	All vaccines
Eligible comp. (e.g. unexpected injury, disability or death, etc.)	Injury that exceeds a normal post-vaccine reaction	Any injury directly attributable to vaccine	Disability or death	Serious injury	Damages above 3,000 Danish kroner	Any injury beyond normal post-vaccine reaction	Injuries listed in FASS or medical literature
Types of comp. (e.g. medical costs, funeral, disability pension, death benefits, lost wages, etc.)	Costs: medical, funeral; disability pension, non-economic loss, death benefits; supplemental payments if disability lasts for more than 6 months	Costs: medical, funeral; disability pension, non-economic loss, death benefits, losses to relatives	Costs: medical, funeral; disability pension, non-economic loss, death benefits, bereavement pension	Lump-sum compensation up to 70,000 Swiss francs, according to set rules	Costs: medical; disability pension, death benefits, non-economic loss, pain and suffering, additional expenses and losses arising from injury less statutory benefits	Medical costs, disability pension, death benefits, earnings support for dependents, lump-sum for impairment	Medical costs, disability pension, non-economic loss, death benefits, lost wages, pain and suffering, additional expenses and losses arising from injury less statutory benefits
Funding	General revenues of state govs.	National Treasury	Multiple levels of gov.: treasury (50%), prefecture (25%), municipal (25%)	General Revenues (federal gov. and Canton)	National Treasury	Specific Tax Revenue (e.g. taxes on employers, wage earners, auto licensing and fuel, gov. investment income)	Contributions from pharmaceutical companies (manufacturers' levy based on % of annual sales)

Jurisdiction	U.K.	Quebec	U.S.	Taiwan	Italy	Norway
Year	1979	1988	1988	1988	1992	1995

[1] Reflects vaccine injury compensation for National Immunization Programme (NIP) vaccines only. Non-NIP vaccines are funded by the pharmaceutical industry.

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Administration	Dept. for Work & Pensions	Provincial Ministry of Health and Social Services	Dept. of Justice, Dept. of Health and Human Services, Office of Special Masters, U.S. Court of Federal Claims	Ministry of Health and Welfare	Ministry of Health	Ministry of Health and Social Services
Vaccines covered	Gov. recommended. / Listed in legislation	Gov. recommended / Listed in legislation	Gov. recommended / Listed in legislation	All mandatory and emergency vaccines	Mandatory and recommended vaccines	Gov. recommended vaccines
Eligible comp. (e.g. unexpected injury, disability or death, etc.)	Injury resulting in > 60% permanent disability	Serious injury or death	Any injury likely caused by vaccine	Injuries listed on the Table of Injuries	Permanent injury or death	Damages above 10,000 Norwegian kroner or 15% disability
Types of comp. (e.g. medical costs, funeral, disability pension, death benefits, lost wages, etc.)	Lump sum payment up to GBP 120,000	Medical costs, disability pension, non-economic loss, rehabilitation, death benefits	Medical costs, disability pension, lost wages, non-economic loss, future care costs, death benefits, attorney's fees	Costs: medical, funeral, illness, impairments, other events; disability pension, non-economic loss, death benefits	Medical costs, disability pension, non-economic loss, death benefits	Medical costs, disability pension, non-economic loss, death benefits, pain and suffering, additional expenses and losses arising from injury less statutory benefits
Funding	National Fund	Provincial Ministry of Health and Social Services	Excise Tax (USD 0.75 on every dose distributed)	Tax on vaccines (USD 0.034 per dose) and local gov. funds	National Treasury	National Treasury & contributions from pharmaceutical industry (manufacturers' levy)

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Table 3: Summary of vaccine-injury compensation programme approach and approaches to pandemic vaccines.

Jurisdiction	AEFI / ADR / DTI	Are pandemic vaccines covered?	Likelihood of COVID-19 vaccine covered existing programme
North America			
Quebec	AEFI	Yes (probable)	Possible
U.S.	AEFI	Yes (covered under CICP)	COVID will fall under CICP
Nordic Countries			
Denmark	DTI	Yes (probable)	Probable
Finland	DTI	Yes (probable)	Probable
Norway	DTI	Yes (probable)	Probable
Sweden	DTI	Yes (probable)	Probable
Iceland	DTI	Yes (probable)	Probable
European Countries			
Austria	AEFI	Yes (probable)	Probable
France	AEFI	If mandatory (probable)	Only if COVID is mandatory (probable)
Germany	AEFI	If gov. recommended (probable)	Only if gov. recommended (probable)
Hungary	AEFI	If mandatory (probable)	Only if COVID is mandatory (probable)
Italy	Insufficient data	If mandatory or gov. recommended (probable)	Only if COVID is mandatory (probable)
Latvia	DTI	Yes (probable)	Probable
Luxembourg	Insufficient data	If gov. recommended (probable)	Only if gov. recommended (probable)
Slovenia	Insufficient data	If mandatory (probable)	Only if COVID is mandatory (probable)
Switzerland	AEFI	If gov. recommended (probable)	Only if gov. recommended (probable)
U.K.	AEFI	No	Unlikely

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Asian Countries			
China	AEFI	If government recommended (probable); if voluntary, up to private insurance scheme (possible)	If gov. recommended (probable); if voluntary (possible)
Japan	AEFI	If government recommended (probable); if voluntary, up to private insurance scheme (possible)	If gov. recommended (probable); if voluntary (possible)
Nepal	AEFI	If gov. recommended (probable)	Only if gov. recommended (probable)
Republic of Korea	AEFI	If government recommended (probable); if voluntary, private insurance scheme (possible)	If gov. recommended (probable); if voluntary (possible)
Taiwan	Insufficient data	If listed as a mandatory or emergency vaccine (probable)	Probable
Vietnam	AEFI	If included in national immunization programme (probable)	If gov. recommended (probable)
Oceania			
New Zealand	DTI	Yes (probable)	Probable

Note: Thailand and Russia have been excluded due to a lack of data.
AEFI: Programmes dedicated to compensating Adverse Events Following Immunization
DTI: Programmes dedicated to compensating Drug and/or Treatment Injuries
Probable: programme is very likely to cover pandemic vaccines if conditions are met.
Possible: it is possible programme will cover pandemic vaccines if conditions are met.

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Table 5: Updated US National Vaccine Injury Compensation Program Statistics

Year	Petitions Filed	Claims Adjudicated	Compensated	Dismissed	Attorney's Fees	Compensation	Total Outlays
1989	148	21	9	12	$54,107.14	$1,317,654.78	$1,371,761.92
1990	1492	133	100	33	$1,379,005.79	$53,252,510.46	$54,689,215.73
1991	2718	588	141	447	$2,364,005.79	$95,980,493.16	$98,842,060.88
1992	189	653	166	487	$3,001,927.00	$94,538,071.30	$98,752,676.41
1993	140	713	125	588	$3,262,453.00	$119,693,267.87	$125,402,993.34
1994	107	608	162	446	$3,571,179.00	$98,151,900.08	$104,889,607.08
1995	180	735	160	575	$3,652,770.00	$104,085,265.72	$110,014,172.00
1996	84	570	162	408	$3,096,231.00	$100,425,325.22	$105,885,679.89
1997	104	387	189	198	$3,898,284.00	$113,620,171.68	$119,397,874.59
1998	120	325	144	181	$4,002,278.00	$127,546,009.19	$133,484,353.24
1999	411	237	98	139	$2,799,910.00	$95,917,680.51	$101,024,548.76
2000	163	229	125	104	$4,112,369.00	$125,945,195.64	$131,782,015.96
2001	216	174	86	88	$3,373,865.00	$105,878,632.57	$111,318,723.12
2002	957	208	104	104	$2,653,598.00	$59,799,604.39	$63,109,448.07
2003	2592	156	56	100	$3,147,755.00	$82,816,240.07	$87,509,650.06
2004	1214	309	62	247	$3,079,328.00	$61,933,764.20	$66,211,708.71
2005	735	289	60	229	$2,694,664.00	$55,065,797.01	$59,551,048.33
2006	325	262	69	193	$2,441,199.00	$48,746,162.74	$52,540,994.37
2007	410	218	82	136	$4,034,154.00	$91,449,433.89	$97,175,608.51
2008	417	298	147	151	$5,191,770.83	$75,716,552.06	$83,556,982.40
2009	397	391	134	257	$5,404,711.98	$74,142,490.58	$85,345,704.64
2010*	448	510	180	330	$5,961,744.40	$179,387,341.30	$189,261,439.67
2011	386	2008	266	1742	$9,572,042.87	$216,319,428.47	$233,482,659.44
2012	401	2798	265	2533	$9,241,427.33	$163,491,998.82	$186,803,360.70
2013	504	1019	369	650	$13,543,099.70	$254,666,326.70	$276,676,893.56
2014	633	563	370	193	$12,161,422.64	$202,084,196.12	$223,563,646.17
2015	803	661	519	142	$14,445,776.29	$204,137,880.22	$225,219,939.33
2016	1120	883	698	185	$16,225,881.12	$230,140,251.20	$252,610,672.33
2017	1243	898	696	202	$22,045,785.00	$252,245,932.78	$282,099,306.34
2018	1238	743	544	199	$16,658,440.14	$199,588,007.04	$226,503,978.61
2019	1282	822	641	181	$18,991,247.55	$196,217,707.64	$225,457,657.94
2020	929	640	494	146	$15,725,728.13	$169,069,146.70	$193,870,498.99
Total	22106	19114	7477	11637	$221,788,160.70	$4,053,370,440.11	$4,407,406,881.09

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Table 6a: Updated summary of programme statistics in Quebec

Summary Statistics compiled April 1st, 2020	
Claims submitted since 1988	284
Number of claims that were not pursued	44
Number of claims pending evaluation	6
Number of evaluation committees to have rendered a decision (only claims meeting the admissibility criteria were evaluated by a medical committee)	196
Number of claims accepted	53
Total number of appeals lodged with the TAQ	83
Total amount of compensation paid	$6,523 M
Total number of cases in which appeals were lodged with the Tribunal administratif du Québec (TAQ)	83
Number of rejected appeals	41
Total accepted appeals – causal relationship	2
Total accepted appeals – disputed compensation amounts	4
Total withdrawn	27
Pending cases	3

Source: https://www.quebec.ca/en/health/advice-and-prevention/vaccination/vaccine-injury-compensation-program/#c3895

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Table 6b: Updated claims information in Quebec by year

Year	Number of completed claims submitted	Number of claims evaluated by a committee*	Number of claims compensated
Before 2000	89‡	74	19
2000	5	4	0
2001	3	3	0
2002	1	1	0
2003	4	4	2
2004	5	5	2
2005	7	2	1
2006	5	5‡	0
2007	4	3	1
2008	3	2	0
2009**	11	8	0
2010**†	16	15	6
2011**†	9	8	1
2012**†	28	27	2
2013	4	2	2
2014	7	6	2
2015†	11	6	3
2016†	9	8	2
2017†	7	9	0
2018	5	3	1
2019	3	0	7
2020	3	1	2
Total	239	196	53

* Only claims meeting the admissibility criteria were evaluated by a medical committee.

** During the 2009–2010 period, 5.7 million Quebecers received the influenza A(H1N1) vaccine, which could explain the increase in claims observed in the three years following the vaccination period observed increase in claims.

† Some claims are pending evaluation.

Source:https://www.quebec.ca/en/health/advice-and-prevention/vaccination/vaccine-injury-compensation-program/#c3895

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Table 7a: New Zealand ACC Number of Vaccination Related Treatment Injury: Claims decided, by financial year of decision (updated)

Financial year claim decided	Decision		Total
	Accept	Decline	Decided
2005/06	73	62	135
2006/07	58	71	129
2007/08	75	62	137
2008/09	67	68	135
2009/10	79	92	171
2010/11	75	71	146
2011/12	85	56	141
2012/13	105	75	180
2013/14	106	74	180
2014/15	121	93	214
2015/16	103	90	193
2016/17	137	106	243
2017/18	104	100	204
2018/19	113	123	236
2019/20*	73	69	142

FOI:Official information Act Request: dated 30 March 2020 Mr. Ahmed Al-Jumaily

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Table 7b: Accepted vaccination related treatment injury claims where the vaccine administered is name in New Zealand ACC (updated)

Accepted Vaccination Related Treatment Injury claims where the vaccine administered is named	
Vaccine	**Count**
Influenza Virus Vaccine	337
MMR Vaccine	200
Tetanus Toxoid	198
DPPT Vaccine	154
Diphtheria Immunoglobulin	100
Pneumococcal Vaccine	85
Tetanus Immunoglobulin	69
Meningococcal Vaccine	64
Pertussis Vaccine	59
Gardasil	46
BCG Vaccine	41
Poliomyelitis Vaccine	40
Hepatitis B Vaccine	40
DTaP-IPV Vaccine	28
Hepatitis A Vaccine	21
Varicella Virus Vaccine (Chicken Pox)	6
DTPA Vaccine	<4
Rabies Vaccine	<4
Typhoid Vaccine	<4
Other/Unspecified	146
Total (ALL)	**1,639**

Note: Some claims arise from multiple vaccines being administered at the same time. These claims are counted more than once.

FOI: Official information Act Request: dated 30 March 2020 Mr. Ahmed Al-Jumaily

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Table 8a: UK Vaccine Payment Damage Claims and Awards

Year	Claims	Awards	Total Amount Paid (initial)	Total Amount Paid (top up)	Comment
				See Note 4	
1977/78	6	0			
1978/79	1,712	36	£360,000	£2,448,000	See Note 1
1979/80	874	317	£3,170,000	£21,420,000	
1980/81	121	256	£2,560,000	£17,272,000	
1981/82	72	68	£680,000	£4,624,000	
1982/83	98	38	£380,000	£2,584,000	
1983/84	101	40	£400,000	£2,720,000	
1984/85	111	36	£360,000	£2,448,000	
1985/86	64	24	£250,000	£1,628,500	
1986/87	76	17	£210,000	£1,142,000	
1987/88	66	10	£160,000	£659,000	
1988/89	38	3	£40,000	£200,500	
1989/90	51	3	£60,000	£197,000	See Note 3
1990/91	34	1	£10,000	£68,000	
1991/92	43	7	£120,000	£458,500	
1992/93	49	13	£320,000	£821,000	
1993/94	54	3	£50,000	£197,000	
1994/95	78	7	£160,000	£446,500	
1995/96	70	6	£170,000	£372,000	
1996/97	69	5	£130,000	£314,000	
1997/98	202	3	£90,000	£184,500	
1998/99	135	0			
1999/00	90	4	£110,000	£249,000	
2000/01	202	2	£50,000	£126,000	
2001/02	146	3	£230,000	£61,500	
2002/03	417	5	£500,000		
2003/04	165	5	£410,000	£68,000	
2004/05	111	4	£400,000		
2005/06	106	5	£500,000		
2006/07	60	4	£310,000	£68,000	
2007/08	53	2	£200,000		
2008/09	62	0			
2009/10	62	3	£230,000	£61,500	

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2010/11	91	1	£30,000	£61,500	
2011/12	91	0			
2012/13	85	0			
2013/14	111	0			
2014/15	79	0			
2015/16	85	3	£340,000		
2016/17	52	2	£240,000		
2017/18	71	3	£360,000		
2018/19	65	1	£100,000		
TOTALS	**6,328**	**940**	**£13,690,000**	**£60,900,000**	

Note 1: Includes 20 payments that do not show a date paid on the database
Note 2: Information calculated by the VDPU up to and including 31/12/2018
Note 3: Includes overpayment of £3,500
Note 4: This information shows the amount paid as Top Up payments in respect of the awards shown in the yearly breakdown. It does not reflect the actual date the top up payments were made as this information is not readily available.
Note 5: This information is accurate to the date shown in note 2. It has been compiled by the VDPU who are responsible to maintaining data relating to claims received under the Vaccine Damage payments Act 1979.
The information contained herein can be made available to the public domain.
Freedom of Information Request Reference FOI-1161672

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Table 8b: Breakdown of Payment Amounts in the UK

Year amount awarded changed	Amount	No. of Payments	Total Paid
	£10,000.00	845	£8,450,000.00
From 1985	£20,000.00	29	£580,000.00
From 1991	£30,000.00	28	£840,000.00
From 1998	£40,000.00	2	£80,000.00
From 2000	£100,000.00	29	£2,900,000.00
From 2007	£120,000.00	7	£840,000.00
	TOTALS	940	£13,690,000.00

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Table 9: Updated overview of no-fault compensation programs for vaccine-related injuries: 5 case studies.

Country (Year Implemented)	QUE (1988) Compensation for victims of vaccination program	UK (1977) Vaccine Damages Payments Unit, Department for Work and Pensions	US (1988) United States National Vaccine Injury Compensation Program	US PREP (2005) Countermeasures Injury Compensation Program 2009 Pandemic H1N1	NZ (2005) Accident Compensation Corporation
Civil Litigation for vaccine-related injuries	No restrictions	No restrictions	Restricted civil litigation. Must first proceed through Vaccine Court	Blanket manufacturer and HCP liability against injuries associated with emergency interventions	Civil litigation for treatment injuries is statute-barred
Total cases adjudicated since program inception (average per annum)	196 (6)	6,407 (151) *includes spike in 1978 of 1,712 cases	19,114*(617)	54 from Mar 2011related to 2009 Pandemic (na)	2,586 (175)
Average annual case load (per million)	(since 2000) 0.8	(since 1978) 2.6 NB: unchanged	(since 1999) 2.15	(since 1989) 2.05	(2005-2019) 39
Average # of awards per year per million	Since 2000 0.2	0.4	.76	Est.* .08 or less than <25 total	20.8
Average # of awards per year per million	Since 2000 0.2	0.4	.76	Est.* .08 or less than <25 total	20.8
Eligibility Criteria					
Vaccines Covered	Any vaccine targeting a vaccine-preventable disease listed in the Public Health Act, e.g. diphtheria	Specific vaccines listed in the regulations of the *Vaccine Damages Payments Act* (largely restricted to those given to <18yrs); includes adult annual influenza vaccines	Specific vaccines listed in *Vaccine Injury Table*(statutory) maintained by Health and Human Services, e.g., polio vaccines	H1N1 vaccines (smallpox and anthrax programmes excluded)	Any vaccine given by a recognised health professional in New Zealand

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Filing Deadlines	3 years after death or onset of symptoms	6 years after immunization	2 years after death; 3 years after symptom onset	1 year after receiving vaccine	1 year after injury onset
Proof Needed	Balance of Probabilities Determined by Expert Review	Balance of Probabilities Determined by Expert Review	Meets Table of Injuries Criteria Balance of Probabilities (3 Prong Standard to prove causation)	Table of Injuries Expert Panel Review	Balance of Probabilities Determined by Expert Review
Type of Injury	Any serious permanent injury	Sole cause of disability; 60% disability	Table injuries or proven injuries	Table Injuries	Any demonstrated injury leading to damages
Causality Assessment Processes	3 – Member Expert Panel Adjudication (petitioner nominates 1 member)	Expert Review	Table of Injuries; Judicial Review	Expert panel review	Expert Review
Compensation	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic, attorney's fees	(1) reasonable and necessary medical services and items to diagnose or treat a covered injury or its health complications; (2) lost wages; and (3) a death benefit for certain survivors. Unsuccessful requesters can motion the Secretary of Health and Human Services to review the determination	Medical costs, disability pension, death benefits
Appeals Process	Yes	Yes	Yes	Yes	Yes
Number that Appeal	50/99	Approx 1/5 (20%)* data up to 2009	Approx 45 for 2009	Unknown	Unknown

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Legal Representation	Limited (except in appeals)	Limited (except in appeals)	Nearly all claimants	None required	None
Legal Fees	Not routinely Costs awarded in several appeal cases.	None	Legal fees reimbursed for both successful and unsuccessful cases.	None	None
Evidence for Averted Civil Litigation	Yes-anecdotal	Yes-anecdotal	Yes (published studies, internal government review, anecdotal)	Yes-blanket indemnification protects HCA and manufacturers	N/A

Sources: US CICP https://sites.suffolk.edu/jhbl/2020/03/22/hhs-grants-broad-liability-immunity-against-future-claims-related-to-covid-19-countermeasures/; Roos, Rover, Mar 16 2011, HHS: 386 injury claims filed over H1N1 countermeasures, Center for Infectious Disease Research and Policy, https://www.cidrap.umn.edu/news-perspective/2011/03/hhs-386-injury-claims-filed-over-h1n1-countermeasures

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UNIVERSITY OF TORONTO

MUNK SCHOOL BRIEFINGS

February 2011

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By Jennifer Keelan PhD
Dalla Lana School of Public Health, University of Toronto
Comparative Program on Health and Society Review Committee, 2006-
Comparative Program on Health and Society Post-doctoral Fellow, 2005-6

and

Kumanan Wilson MSc, FRCP(C)
Department of Medicine, Ottawa Hospital Research Institute, University of Ottawa

For the CIHR funded Canadian No-Fault Compensation for Vaccine-related Injuries Working Group

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978-0-7727-0847-2
ISSN 1715-3484

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By Jennifer Keelan PhD, Kumanan Wilson MSc, FRCP(C)
February 2011 ISBN 978-0-7727-0847-2

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Acknowledgements

We would like to thank the peer reviewers for their insightful comments. Dr. Keelan is supported by an Ontario Ministry of Health and Long-term Care Career Scientist Award. Dr. Wilson is supported by a Canada Research Chair in Public Health Policy. This report was a supported by a grant from the Canadian Institutes for Health Research. We would also like to thank Teela Johnson and Leslie Beard who served as project coordinators for this research project. In addition, we would like to thank Jean-Francois Letourneau for conducting the French-language interviews.

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Designing a No-Fault Vaccine-Injury Compensation Programme for Canada: Lessons Learned from an International Analysis of Programmes

Jennifer Keelan PhD
Kumanan Wilson MSc, FRCP(C)

EXECUTIVE SUMMARY

This report provides both an in-depth analysis of several distinct types of no-fault programmes and research-based recommendations for the design and implementation of a model programme that could be implemented in the Canadian context. To do so, we reviewed the international programmes implemented in thirteen jurisdictions and conducted in-depth case studies of the programmes implemented in the United States, the United Kingdom, New Zealand and in the province of Quebec.

Why Canada needs a no-fault compensation programme for vaccine-related injuries

Immunization programmes are considered a corner-stone of Canadian public health and are responsible for the dramatic decline in the incidence and severity of many vaccine-preventable diseases. However, every year in Canada, despite the best practices of both vaccine manufacturers and health care professionals, a few individuals will sustain serious harm and bear the burden of this harm while contributing to a public good. In these cases, there is a compelling argument that those who are injured should receive compensation through a no-fault programme.

The core argument for implementing government compensation for vaccine-related injuries hinges on the ethical principle of reciprocity. While not strictly mandatory, many vaccinations are intended not only for the protection of the vaccinated but also for the protection of others (Harris and Holm 1995; Krantz et al. 2004; Ross 2005; Salmon et al. 2006). When vaccination rates hit a particular threshold and are sustained, the transmission of the pathogen from person to person is disrupted and the incidence of the disease falls accordingly. This property of vaccination programmes, known as *herd immunity*, also protects those in the community who, for a variety of reasons, cannot be vaccinated, are ineffectively vaccinated, or refuse to be vaccinated. As a consequence, governments all over the world have introduced policies to maximize vaccination rates – for example requiring a suite of vaccinations for school attendance or requiring health care workers to show proof of immunization against a variety of vaccine-preventable diseases. Thus when someone is seriously injured because they participated in a government vaccination programme (and contributed to a broader public good), there is an ethical argument for providing compensation for the injuries sustained, which frequently include lost wages, uninsured medical costs, and rehabilitative supports (Rea and Upshur 2001).

No-fault compensation programmes have been introduced in at least 13 jurisdictions around the world, including the province of Quebec. Canada stands alone with Russia as the only two G8 nations to not have a national programme.

Utility of a no-fault approach

Since the injuries related to vaccines generally occur despite best practices in both manufacturing and delivery, injured parties in Canada cannot use negligence to establish fault (Kutsela 2004; Manitoba Law Reform Commission 2000; Peppin 2005). In addition, most vaccine-related injuries are idiosyncratic in

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nature making it nearly impossible to predict who might have a serious adverse event (Institute of Medicine 1985; Jacobson et al. 2001). Though there have been many Canadian vaccine injury cases tried over the past few decades in Canadian courts, *because of these features of vaccine injury there has not been a single successful vaccine injury case in Canada* (Manitoba Law Reform Commission 2000). This has led several of the presiding judges in these cases to include in their judgments an acknowledgement of the unfairness of a legal system that lacks the mechanism to provide compensation in cases where people are clearly injured while participating in a public good (see for example *Morgan v City of Toronto*).

A no-fault approach for vaccine-related injuries includes the following features:

- The recognition that there are situations of *unavoidable* or *unintended* medial injuries that merit compensation. Traditional tort litigation on the other hand is premised on the principle aim to punish wrong-doings (punitive) and to deter the public from doing harm to others (deterrence).
- Because there is no fault presumed, compensation is needs-based rather than punitive, and is, thus, both relatively *modest* and *proportionate* to the injury.
- Unlike jury trials, no-fault compensation processes are more likely to be *consistent* both in the type of *award* and in the *amount of compensation*.
- No-fault programmes can *rapidly* resolve injury claims by either using a fixed table of vaccine-associated injuries or an administrative or judicial review of each case (as opposed to civil litigation which is adversarial, prohibitively expensive, and nearly always more time consuming) (Bismark and Paterson 2006).
- No-fault compensation programmes move vaccine injury cases out of the tort arena into a publicly administered or regulated programme saving vaccine manufacturers hundreds of millions of dollars in legal fees, help to stimulate vaccine innovation and manufacturing thereby keeping the costs of vaccines low for public programmes (Evans 2006).
- Giving those injured access to a reasonable, restitutive process weakens the power of vaccine's fiercest critics.

Lessons learned from other jurisdictions

How are no-fault programmes typically run?

- Worldwide, most no-fault programmes are government-run and national in scope. They generally fall under the administration of state ministries related to health and social welfare or labour (as in the case of the United Kingdom) or there is federal/national legislation that governs an arms-length overseeing agency, as in the case of New Zealand. Only in Sweden is the no-fault programme covered under a private drug insurance scheme (see Table 1).

What vaccines are usually covered?

- Most no-fault compensation programmes were implemented in the 1970s and 1980s when vaccine programmes targeted infants and school-aged children. Thus, some programmes restrict eligibility for compensation to government recommended vaccinations given to infants and children. In some instances, vaccinations required by state mandates are included in the programme.
- In the case studies we examined, the programmes covered most government recommended vaccines (including adults) or any vaccines administered by a recognised health professional. In many cases, there is supporting legislation that either lists vaccines by name, as in the United Kingdom, or covers all vaccines related to the listed vaccine-preventable diseases, as in Quebec's programme (see Table 2).

How does a claimant demonstrate that the vaccine caused an injury?

- Most no-fault programmes are designed for an administrative review of the injury, similar to other accident insurance or disability schemes, and do not require the claimant to seek legal representation or solicit expert medical review (beyond their attending physician's report).

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- The assessment of claims is typically overseen by a medical director and follows a combination of an administrative review of eligibility criteria and a medical assessment performed by outside consultation from medical experts (as in the United Kingdom and New Zealand).
- Only the US has a system that resembles civil litigation, with the government acting as the defendant and the injured party as the plaintiff in each case. Both parties are represented by lawyers, produce expert witnesses, and argue their cases before a special master (specialized judges). Also unique is the province of Quebec's tribunal system where claims are heard by a three-person medical tribunal and decided by a 2/3 majority opinion. One tribunal member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.

What types of medical and non-medical costs do most programmes cover?

- Most programmes are designed to cover *uninsured* medical costs, while others include special disability benefits, death benefits, economic damages (lost wages) and, in some cases, non-economic losses. New Zealand is unique in that it compensates for all unexpected injuries with a demonstrable economic loss, e.g. a sore arm that resulted in lost work would be compensable. The United States also compensates all injuries that result in measurable damages, whereas the United Kingdom has a high threshold, requiring over 60% permanent disability caused *solely* by an adverse event following immunization. Similarly, Quebec only compensates in cases of serious injury or death.
- Only the United States routinely covers the claimant's legal fees because its system is structured to require legal representation.
- In many jurisdictions, the settlement amount is calculated by agencies that typically deal with disability or accident claims. Compensation is frequently determined according to the rules governing accident or disability scales (as in Quebec) or determined by a life-planner (as in the United States). Lump sum settlements are issued in jurisdictions where there is a strong social safety net such as the United Kingdom & Norway.

How are most programmes funded?

- Because no-fault programmes for vaccine-related injuries tend to be fairly modest in scale, compared to other entitlement programmes, most are funded from general revenues. In the United States, the programme is funded by a special vaccine excise tax (paid by the purchasers) and in Sweden, Taiwan and Norway, a premium is paid by the vaccine manufacturer's themselves.

How predictable are the number of claims and settlements among the various no-fault compensation programmes and what kinds of programme components impact the overall payouts?

- Despite radical differences in approaches, administration, and eligibility criteria, data from all four jurisdictions studied shows that the average number of claims and compensation amounts are relatively stable and predictable and represent both an affordable and reasonable expenditure as part of an overall national vaccination immunization programme. Still, the predicted number of settlements and the cost of any scheme does depend greatly on eligibility criteria, filing requirements, and the public's knowledge of the programme.
- The number of cases compensated is directly related to the eligibility requirements imposed by each system.

Design of a Canadian no-fault compensation programme–our recommendations

Our review of the lessons learned from international programmes and the four case studies has led us to the following recommendations for a national compensation programme for adverse events following vaccination.

- The principle aim of a Canadian no-fault compensation programme should be to fairly compensate those likely injured from a vaccine recommended by the federal government through agencies such as the National Advisory Committee on Immunization (the organization charged with a routine review of

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vaccination) or through official recommendations of the Public Health Agency of Canada (e.g., made during the emergency release of a vaccine during an outbreak or pandemic).

- The programme should ideally be administered by an arms-length agency, e.g., the Public Health Agency of Canada, but independent of the branches of government responsible for the promotion and safety of vaccines.
- Based on international experiences, a reasonable statute of limitations for filing claims should be set (e.g., 3 years from injury onset), in addition to requiring sufficient documentation to substantiate the injury and its aetiology.
- The injury itself must result in some measurable *uninsured* damages or costs. In the case of death, a death benefit would be paid out similar to an accidental death insurance benefit.

Proposed adjudication of claims process (See Figure 1)

STEP 1. Determine basic eligibility criteria are met.

STEP 2. The claimant, in consultation with the programme's administrator, would have the choice of:

1. Table of Injury Review: Claimants can choose to have their case proceed to a Table of Injuries Review, a review based on a predetermined table listing all NACI recommended vaccines and scientifically substantiated adverse events associated with the listed vaccines. If a claimant meets the pre-existing Table of Injury requirements (see Figure 1), compensation would be granted.
2. Individual Case Review (Tribunal): In cases where the claimant's injury does not fall on the Table of Injuries, the claimant could choose a committee hearing overseen by a Special Master. The claimant would have the power to appoint one committee member, the Public Health Agency of Canada would appoint a second, and the third member would be decided by consensus of the two appointed members. Each committee member would be tasked with reviewing the case and presenting a reasoned opinion to the Special Master who would be empowered to make a binding decision. In these cases, causation would be determined by meeting a three-prong causality test which includes establishing a i) biological theory of harm; ii) logical sequence connecting vaccine to injury; and iii) temporal association of the injury with a vaccine. No other more probable explanation for the injury is established in the proceedings.

STEP 3. Once a claim is decided as compensable in principle, either through a table process, or individual case review, the degree of disability and compensation would ideally be determined by a federal bureau with expertise in adjudicating disability claims.

Annual review and audit

The Table of Injuries would be created and annually updated by a federal advisory committee, likely in cooperation with existing advisory committees such as the National Advisory Committee on Immunization (NACI). Annual audits of claims and settlements would be used to further refine and tailor the Table of Injuries. In addition, a Table of Disallowances could be populated to deal with common or popular theories of harm where there is a substantial body of evidence to summarily deny an association between vaccines and particular injuries.

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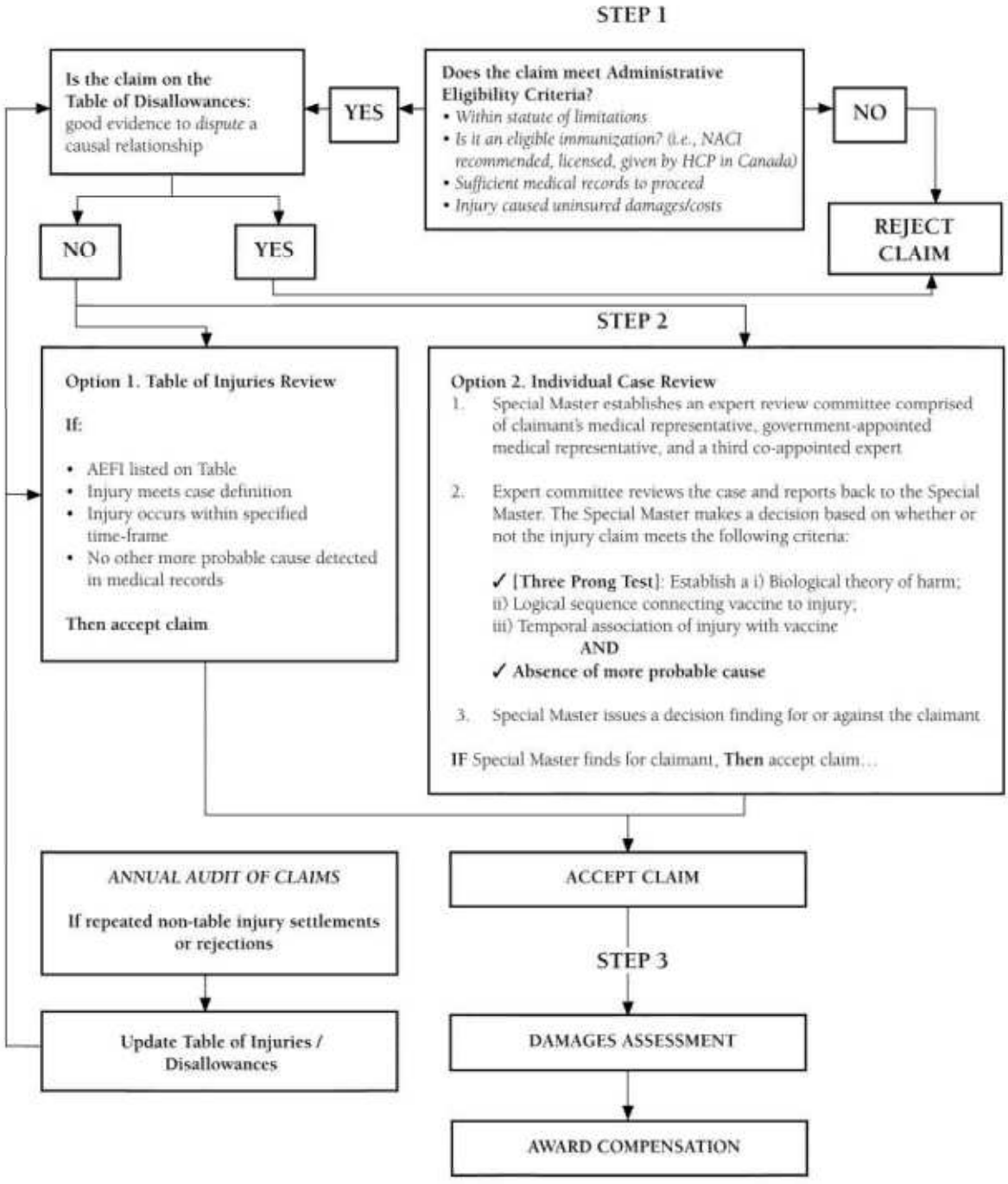
Figure 1. Proposed adjudication process for a national, no-fault compensation programme for vaccine-related injuries


STEP 1
Is the claim on the Table of Disallowances: good evidence to dispute a causal relationship
YES
Does the claim meet Administrative Eligibility Criteria?
• Within statute of limitations
• Is it an eligible immunization? (i.e., NACI recommended, licensed, given by HCP in Canada)
• Sufficient medical records to proceed
• Injury caused uninsured damages/costs
NO
NO
YES
REJECT CLAIM
STEP 2
Option 1. Table of Injuries Review
If:
• AEFI listed on Table
• Injury meets case definition
• Injury occurs within specified time-frame
• No other more probable cause detected in medical records
Then accept claim
Option 2. Individual Case Review
1. Special Master establishes an expert review committee comprised of claimant's medical representative, government-appointed medical representative, and a third co-appointed expert
2. Expert committee reviews the case and reports back to the Special Master. The Special Master makes a decision based on whether or not the injury claim meets the following criteria:
✓ [Three Prong Test]: Establish a i) Biological theory of harm; ii) Logical sequence connecting vaccine to injury; iii) Temporal association of injury with vaccine
AND
✓ Absence of more probable cause
3. Special Master issues a decision finding for or against the claimant
IF Special Master finds for claimant, Then accept claim…
ANNUAL AUDIT OF CLAIMS
If repeated non-table injury settlements or rejections
Update Table of Injuries / Disallowances
ACCEPT CLAIM
STEP 3
DAMAGES ASSESSMENT
AWARD COMPENSATION

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BACKGROUND

In 1972, a five year old girl in Quebec named Nathalie Lapierre received a measles vaccination and, subsequently, developed viral encephalitis and severe, permanent disabilities. Her father, Jacques Lapierre, launched a lawsuit against the Quebec government for compensation for the harm sustained. Initially, the Superior Court of Quebec found that while no one was at *fault* for Nathalie's serious injuries, her case merited compensation because it was an undisputed fact that her injuries were caused by complying with a government recommended vaccination schedule, and such compliance was of benefit to the community. This ruling was subsequently over-turned by the Supreme Court of Canada who maintained that Quebec law did not allow awarding a settlement when there was no *fault* in the delivery or manufacturing of a vaccine (Ministère de la Santé et des Services Sociaux Québec 2011; Templeman-Kluit 2008). As a result, the family's attempt to receive compensation for injuries failed.

In response to the case, in 1986, the Quebec government passed amendments to the Public Health Act to create a provincial no-fault programme to provide compensation for vaccine-related injuries in cases similar to the Lapierre's (R.S.Q., chapter S-2.2, Division III (70-78)). The programme the Quebec government put in place provides compensation to those who developed a serious and permanent injury to any vaccine issued against the vaccine-preventable-diseases listed in the statute *if* a medical tribunal agrees that the vaccine was the most likely cause of the injury (Ministère de la Santé et des Services Sociaux Québec 2011).

There are now at least thirteen countries that have created no-fault vaccine injury compensation programmes (Evans 1999; Isaacs 2004). In Canada, Quebec remains the only province to institute a programme to compensate those injured from immunization despite recurrent recommendations to close this policy gap by professional organizations such as the Canadian Paediatric Society (1986). In one of the earliest statements of support for implementing a programme, the Canadian Paediatric Society recommended implementing a programme in response to a period of heightened public concern over the safety of the diphtheria-pertussis-tetanus (DPT) vaccine, a relatively reactive vaccine then associated with encephalitis and neurological injury (Canadian Paediatric Society 1986). Indeed, many jurisdictions created no-fault compensation programmes to address public concerns over the safety of the DPT vaccine (Canadian Paediatric Society 1986). Federally sponsored workshops or expert-planning exercises designed to coordinate and rationalize immunization policy nationwide have also frequently identified the lack of a mechanism to compensate rare vaccine-related injuries as a policy gap. No-fault compensation for all treatment injuries, including those that are vaccine-related, has also been proposed as part of a broader reform of the Canadian tort system by Justice Krever in the *Commission of Inquiry on the Blood System in Canada* and by Robert Pritchard in *Liability and Compensation in Health Care* (Canadian Paediatric Society 1986; Krever 1997; Pritchard 1990).

In 2001, a report signed by leading vaccine experts reiterated the need for such a programme: "By 2005, every Canadian should have access to a vaccine injury compensation for long-term sequelae caused by vaccines" (Health Canada 2001, 13). The report recommended that the federal government create an expert advisory committee to develop the rationale, programme components, and criteria for compensation. The authors of the report argued that compensation should be based on the findings of a causality assessment and that any programme should be designed to provide all Canadians with an equitable compensation process (Health Canada 2001, 13–4).

Understanding and evaluating no-fault approaches to vaccine-related injuries

The interest in no-fault approaches to vaccine-related injuries has been rekindled to some degree by the recognition of the fact that immunization programmes are becoming increasingly complex and, at the same time, our culture is becoming more sensitive to the risks of immunization. Policy makers are confronted with the ethical and legal dilemma of how to fairly compensate those injured by immunization and it is anticipated that it will become increasingly difficult to maintain public support for recommended immunizations without providing a reasonable process to receive just compensation for legitimate injuries sustained from vaccinating (Wilson 2007). The purpose of this study was to examine the need for and potential utility of a no-fault approach to vaccine indemnification in Canada. To do so, we reviewed the

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history and rationale of vaccine indemnification worldwide and, using four specific case studies, assessed the different approaches to no-fault compensation.

Our study, conducted between 2007 and 2009, consisted of a literature review, semi-structured interviews with key informants, and the analysis of four international no-fault compensation programmes using an analytic framework we developed from existing literature (Isaacs 2004; Ridgway 1999). The aim of the study was to provide both an in-depth analysis of several distinct types of no-fault programmes and to create research-based recommendations for the design and implementation of a model programme that could be implemented in the Canadian context.

The literature review for this study included the identification of research related to no-fault programmes worldwide in social sciences and humanities, legal and medical databases. We also identified any government reports, programme evaluations or reviews that were publicly available. Finally, *access to information* requests provided up-to-date programme data for Quebec, New Zealand, and the United Kingdom (the United States data was largely available through government websites). Ethics approval was obtained to conduct expert informant interviews in Canada, the United States, the United Kingdom, and New Zealand. Drawing on published sources (peer-reviewed research, government reports), access to information requests, and stakeholder informant interviews with programme experts, scientists, representatives of vaccine manufacturers, programme lawyers, claimants, and no-fault policy specialists, we assessed and compared the strengths and weaknesses of the four no-fault compensation programmes we chose as case studies.

In interviews spanning between one to two hours, informants were asked a range of questions related to the history of, rationale for, and overall programmatic structure of the no-fault compensation programme in their jurisdiction. Building on Geoffrey Evan's (1999) descriptive framework of international no-fault programmes world wide, we queried informants on: a range of technical and administrative components related to filing and eligibility requirements (e.g., level of disability, statute of limitations), the rules governing compensation (e.g., what kinds of injuries are compensated), how the connections between injuries and vaccines are established in each system, what vaccines are covered by the programme, how the programme is funded, the possible recourse to traditional tort law for compensation, overall costs of the programmes, and any calculations of cost-savings or benefits attributable to the programme. Informants were also asked to identify perceived strengths and weaknesses in their programmes, make suggestions for reform, and to describe what the features of an ideal approach to vaccine-related injuries would be (see Table 2).

Section I gives an overview of the rationale for vaccine indemnification programmes and a comparison of their implementation in identified jurisdictions. Section II provides a detailed description and analysis of the four international compensation systems examined. After compiling and evaluating the existing programme options, we hosted workshops and solicited expert feedback from stakeholders (vaccine manufacturers and legal advisors, government policy makers and vaccine scientists) to solicit feedback and to assess the feasibility of different components and no-fault models emerging from our analysis. The culmination of this research is the recommendations outlined in Section III of this report.

SECTION I

Why countries have adopted a no-fault approach to vaccine-related injuries

"It is nearly impossible to predict who might suffer an adverse vaccine reaction, absent a known allergy, immunodefficeincy, or pervious neurological deficit." (Mariner 1992, 256)

Universal immunization is a public good

Vaccines are often described as the most effective medical intervention for the prevention of once devastating infectious diseases and are, also, amongst the safest pharmaceutical therapies available. When vaccination rates hit a particular threshold and are sustained, the transmission of the pathogen from person to person is disrupted and the incidence of the disease falls accordingly. This property of immunization programmes, known as *herd immunity*, also protects those in the community who, for a variety of reasons,

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cannot be vaccinated, are ineffectively vaccinated (the immuno-compromised, the very young, and the elderly), or refuse to be vaccinated (Fine 1993).

Immunization though technically voluntary is implemented with coercive policies

The importance of herd immunity has influenced vaccination policy. Vaccinations are not strictly compulsory under federal or provincial laws (Peppin 2005), yet research suggests that current policies to promote vaccination can be viewed as coercive (compelled by force, intimidation, or authority). Increasingly, vaccination is a requirement for participation in public programmes (day-care, camps) and for employment. Those who choose not to be vaccinated against diseases like influenza have been shown to cause risk to fellow citizens, especially if they are in frequent contact with vulnerable subgroups (see for example Carman 2000; Glanz 2009; Simonsen 2005).

In Canada, the promotion and provision of nationally recommended immunizations has become a matter of public policy; provinces and territories have adopted policies known to increase compliance to recommended immunizations (Peppin 2005). Children are required to receive certain vaccinations to attend school or day-care in many jurisdictions. While exemptions can be obtained for medical, philosophical, or religious reasons, the availability of this option is not well publicized. In several healthcare institutions, vaccination is a requirement for employment. In some cases, healthcare workers can opt-out of receiving recommended vaccines, however employers have reserved the right to restrict the employees' duties or temporarily lay-off a worker without pay in the event of an outbreak. In a recent report from the Manitoba Law Reform Commission, the authors argue that there is, "considerable governmental and social pressure to participate in the immunization process" (Manitoba Law Reform Commission 2000, 15; Peppin 2005). For example, a recent survey of paediatricians indicates that parents not wishing to vaccinate their children may face estrangement from health care practitioners (Flanagan-Klygis et al. 2005).

Rare but serious injuries from immunization occur despite best practices

Despite the great benefits from a universally immunized population, side-effects from vaccines have been observed and have the potential to cause serious injuries and permanent harm. Infrequently, injuries can be caused by a particularly "hot" or immunologically reactive batch of vaccine but more often, injuries are related to idiosyncratic and therefore unpredictable immune responses to the immunization, or an underlying predisposition for injury. Injuries caused by vaccines are extremely rare occurring at rates from 1 in 40,000, as in thrombocytopenia after MMR vaccine (France et al 2008), to less than one serious event per million doses, as in Guillain-Barré Syndrome (GBS) related to influenza vaccine (Haber 2004). Because vaccines are given to millions of individuals, even risks as low as these will result in a predictable number of injuries following mass immunization campaigns.

Pre-clinical trials can identify risks that occur at a rate greater than 1 in 10, 000 and post-clinical surveillance can identify risks as rare as 1 in 1 million, thus serious adverse events following immunization are not typically identified before a vaccine is licensed for use, and are not decipherable until the immunization has been used for many years in its target population. Even with years of experience with a particular vaccine technology, the precise aetiology of rare adverse events is often poorly understood and the possible or probable relationship between the adverse event and immunization can remain uncertain despite the best efforts of researchers (Kohl 2005).

Civil litigation is an inappropriate remedy for vaccine-related injuries

For many reasons, civil litigation is not an effective mechanism of redress in cases of vaccine-related injury (Law Reform Commission of Saskatchewan 2007; Manitoba Law Reform Commission 2000; Fowler 2010; Wilson 2007). In his review of the United States' federal swine flu vaccine-injury compensation programme, Richard Gaskins argued that civil litigation fails to provide just compensation for vaccine-related injuries and instead is at high risk for iniquitous, idiosyncratic, and unfair judgments for both manufacturers and claimants.

> Judicial doctrines like duty to warn, informed consent, and assumption of risk, based on paradigms of commercial relations between private individuals, cannot fully capture the responsibilities that hold between

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> the individual and society as a whole. They operate capriciously in some cases to impose unfair costs on manufacturers or the government, in other cases to leave the entire burden of injury on the individual. In addition, the high cost of administering compensation rules through the judicial system imposes unnecessary burdens on plaintiff and defendant alike (Gaskins 1980).

In Canada, there has not been a single successful suit for compensation for an injury sustained from routine vaccination (Law Reform Commission of Saskatchewan 2007; Manitoba Law Reform Commission 2000; Templeman-Kluit 2008). The principle axiom of the common law of torts hinges on the proof of *fault* (Gilmour 2006). It is impossible to be compensated for *unavoidable* injury or injury sustained during activities a normal person would have hazarded (Gilmour 2006; Manitoba Law Reform Commission 2000).

Those injured by adhering to routine immunization could sue the individual health care professional delivering the vaccine, the vaccine manufacturer, or the provincial agency providing the vaccine. However, the plaintiff must show that the injuries sustained were caused by defective manufacturing or design, or negligence in the operation of vaccinating such as failure to secure informed consent, or failure to warn of adverse events (see for example *Lapierre c. P.G. (Qué.)*, [1985] 1 R.C.S. 241); Peppin 2005). In *Reibl v. Hughes* [1980], the plaintiff unsuccessfully argued that he was not fully informed of the risks of vaccination. However, the judge argued that compensation was not merited because an average person would still likely proceed with vaccination despite full disclosure of risks because of the rare nature of vaccine injuries (Manitoba Law Reform Commission 2000).

Litigation for vaccine injuries has other drawbacks. It is adversarial, prohibitively expensive, and time consuming. For example, in the precedent setting *Rothwell v. Raes* (1988), the legal costs exceeded one million dollars, involved over seventy-four days of court time, and it took nine years for a final decision at the Ontario Court of Appeals (Manitoba Law Reform Commission 2000). As Osgoode law professor Joan Gilmour has argued (2006), "Lawsuits are slow, complex, costly despite the greater availability of contingency fees, unpredictable, and in the case of medical liability claims, usually unsuccessful" (74). In the recent vaccine injury case of *Morgan v. City of Toronto* (2006), Judge Sanderson argued that, "... even when it can be credibly postulated that a vaccine has caused serious adverse consequences, the barriers standing in the way of recovery are formidable...Complex and protracted litigation such as this is notoriously costly, given the need for expert scientific evidence and medical proof" (*Morgan v. City of Toronto* 2006, 441).

While vaccine-injured citizens and their families have coverage for a range of medical expenses under provincial and territorial health insurance, they do not receive compensation for all costs sustained. For example, families cannot receive compensation for death (funeral costs), personal suffering, and income loss from permanent disability.

No-fault schemes have the advantage of being able to rapidly resolve injury claims by either using a fixed table of vaccine-associated injuries or an administrative or judicial review of each case. Because there is no fault presumed, compensation is needs-based rather than punitive, and is thus both relatively modest and proportionate to the injury. Most jurisdictions attempted to design their programmes to take advantage of the no-fault approach which the literature suggests would offer more timely and consistent compensation, a more effective process for complaint resolution, improve provider accountability, improve public trust in immunization, contribute to an overall culture of safety, and provide compensation proportionate to injuries sustained (Bismark and Paterson 2006; Dyer 2005; Gilmour 2006; O'Connell 1984; Ridgway 1999; Studdert 2001).

A key component in any no-fault compensation programme is the determination of eligibility rules for compensation. Principally, this involves a causality test (showing that the vaccine *caused* the injury), and other eligibility rules including filing deadlines (statutes of limitations), and the types of vaccines covered by the programme (see Table 1). There are few formal evaluations of no-fault programmes (Bismark and Paterson 2006; Bismark et al. 2006; Gilmour 2006; Studdert 2001), but the principal findings suggest that they have been effective in providing compensation to those likely injured, have reduced civil litigation, and have provided a formal venue to effectively respond to concerns over vaccine safety (Evans 1996; 1999; Isaacs 2004; Ridgway 1999).

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Table 1. Vaccine injury compensation programmes worldwide. Data compiled from Evans 1999 and Isaacs 2004, and government websites. Note that some countries with programmes have been omitted, e.g., South Korea due to lack of data on these programmes. The following abbreviations are used: Denmark (Dnmrk), New Zealand (New Zeal.), Switzerland (Switzer.)

	Germany	France	Japan	Switzer.	Denmark	New Zeal.	Sweden	U.K.	Quebec	U.S.	Taiwan	Italy	Norway
Year	1961	1964	1970	1970	1972	2005	1978	1979	1988	1988	1988	1992	1995
Admin.	State (pension system) under federal regulation	Min. of Health & Solidarity	Min. of Health	States under federal regulation	National Social Security Office	Accident Compensation Corp.(Crown Corp.)	Private Drug Insurance	Dept. for Work & Pensions	Min. of Health and Social Services	Dept. of Justice / Health and Human Services	Dept. of Health	Min. of Health	Min. of Health and Social Services
Vaccines Covered	Gov. Rec.	Required	Gov. Rec.	Gov. Rec.	Gov. Funded	Any given by a health care practitione	All licensed vaccines	Gov. Rec. / Listed in Legis.	Gov. Rec. / Listed in Legis.	Gov. Rec. / Listed in Legis.	All Mandatory	All Mandatory	Gov. Rec./ Children
Eligible Comp.	Un-expected injury	Any injury directly attributable to vaccine	Disability or death	Un-expected serious injury	Any injury likely caused by vaccine	Un-expected injury	Injuries listed in FASS or medical literature	Injury resulting in >60 permanent disability	Serious injury or death	Any injury likely caused by vaccine	Injuries listed on the Table of Injuries	Perm. injury or death	Unknown
Types of Comp.	Costs: medical, funeral; disability pension	Costs: medical, funeral; disability pension, death benefits, non-economic	Costs: medical, funeral; disability pension	Costs: medical, funeral; disability pension, death benefits, non-economic	Costs: medical, death benefits, non-economic benefits	Medical costs, disability pension, death benefits	Medical costs, lost wages, death benefits	Lump sum payment	Medical costs, rehabilitation, death benefits	Medical costs, lost wages, non-economic, attorney's fees	Costs: medical, funeral	Medical costs, disability pension, death benefit	Lump sum
Funding	General revenues	National Treasury	Mulitple Levels of Gov.	General Revenues (Canton)	National Treasury	Specific Tax Revenue	Drug Co.'s premium	National Fund	National Treasury	Excise Tax	Drug Co.'s premium & Local Gov.	National Treasury	National Treasury & Drug Co.'s premium

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The key issues arising from international experiences with no-fault programmes are of three types:

a) Concerns that the causation test and / or eligibility criteria are too restrictive leading to under-compensation of claims which can drive claimants back into the tort system (civil litigation). This, in turn, increases the profile of vaccine injuries and the potential for public controversy over vaccine safety.

b) Concerns that the causation test and / or eligibility criteria are too generous leading to over-compensation of claims which in turn can undermine the public's perception of safety of vaccines.

c) Concerns that the eligibility requirements or administrative processes are onerous or too complex creating unnecessary barriers to access compensation.

The main drivers for policy implementation in other jurisdictions have varied but included the following factors: episodes of widespread concern over vaccine safety, a fall in vaccination rates, surges in civil litigation, vaccine manufacturers threatening to withdraw from the vaccine market, vaccine shortages, the disruption of routine vaccination programmes, and outbreaks from vaccine-preventable diseases.

Canada was largely shielded from these forces. Unlike the United Kingdom, Canada did not experience the same crisis in confidence in government regulatory bodies overseeing the safety of medical treatments (such as thalidomide) that drove the United Kingdom to implement an indemnities policy (Baker 2003). Unlike the United States, Canada was not driven to implement a no-fault compensation programme to protect the vaccine supply.

The *absence* of the political, economic, and social pressures, that propelled the implementation of policies in other jurisdictions, reduced the impetus for the development of a Canadian solution to rare vaccine adverse events, despite expert support for the idea and the enduring ethical arguments to do so. However, there are several indicators that suggest that the parameters that kept no-fault compensation off the political agenda are subject to change (Picard 2002).

Changes to the legal environment

Recent changes to the rules on the formation of national class-action lawsuits raise the spectre of inter-provincial and even international cooperation in supporting lawsuits against manufacturers for alleged vaccine-related injuries. Even if civil cases are not likely winnable in Canada, the risk of litigation, as in a recent B.C. class action vaccine-injury case (Kent 2003), can cost manufacturers tens of millions of dollars. While data on the manufacturer's legal costs related to vaccine injury are not currently available, in a recent review of the no-fault issue by the Saskatchewan Law Reform Commission, the authors argued that manufacturers' legal costs in fighting and settling injury cases in Canada are likely high, "...many claims may be settled out of court, though reluctance of manufacturers to publicize law suits makes it difficult to determine the frequency of settlements. Claims are most apt to be settled if liability is clear" (Law Reform Commission of Saskatchewan 2007, 20).

Increasingly complex immunization schedules / targeting adults

While new immunization technologies are significantly safer than those used during the formulation of many indemnification programmes, immunization programmes have become increasingly complex, and the targeted infectious diseases increasingly rare, diminishing the real and perceived benefits-to-risk ratio that is so critical to maintaining public support for immunization.

There is also an increasing number of immunizations targeting adults and employees who must be immunized (e.g., nurses, physicians, allied health care professionals, teachers, day-care workers and child minders), not necessarily for their own benefit, but for public safety. When adults experience even transient, serious, adverse events following immunization, such as Guillain-Barré Syndrome (GBS) following annual influenza immunization, the lost wages and the inconvenience of illness can have a large impact on family income.

Support for vaccines is broad but shallow

As in other jurisdictions, a single high-profile case of vaccine-related injury can mobilise public panic over

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immunization safety. Research has shown that support for immunization is broad but shallow in Canada (Ritvo 2003; Wilson et al. 2006) indicating that a future crisis in public confidence in immunization is probable. Recent research also suggests that it is easier for those injured by immunization to connect with vaccine critics and legal supports via Web 2.0 platforms (Chin et al. 2010; Keelan et al. 2007; Wilson and Keelan 2009). This encourages those injured to align themselves with groups that are highly critical of immunization and suspicious of public health officials. Vaccine critical groups (largely antivaccinationists) are sceptical of the benefits or safety of universal immunization programmes, and have a large and influential online presence. The dissemination of anti-vaccination viewpoints through social networks can amplify the impact of a single vaccine injury case. The lack of recourse or due process for victims of vaccine injury in Canada feeds into the vaccine critical movement (Keelan et al. 2007; Wilson 2007).

The experience of other jurisdictions suggests that in times of crisis (precipitated by public controversy over the safety of immunization, an increase in vaccine-related injury litigation, or a threatened vaccine supply) governments normally enact no-fault compensation programmes to deal with vaccine-related injuries sustained from mass immunization campaigns. The history and experience with vaccine-related injuries in many other western countries also suggests that it is highly probable that Canada will be faced with circumstances that will require the development of a nation-wide indemnities programme or policies to protect vaccine manufacturers from liability. In fact, with the release of the H1N1 vaccine during the 2009 swine flu immunization campaign, the federal government was forced to accept liability for the manufacturer Glaxo-Smith-Kline (GSK) in order to release the H1N1 vaccine in time for the fall of 2009. However, it is unclear how those injured could receive just compensation for H1N1 vaccine-related injuries. Equally unpalatable for the ongoing success of national immunization programmes, are the prospects that injured parties will be forced into lengthy court battles against the federal government or barring any realistic alternative to civil litigation, citizens will turn to the media to vet their concerns and complaints. The reactive design of a no-fault scheme, under such circumstances, or in the wake of a public controversy, would be suboptimal.

Arguments against no-fault compensation for vaccine-related injuries

The obligation to compensate for vaccine-related injuries diminishes if immunizations are purely voluntary

If the goal of government-sponsored immunization programming is purely to provide citizens with the opportunity to take advantage of medical technologies to protect themselves, and *not others*, against vaccine-preventable diseases then the reciprocal responsibilities of government to compensate those injured by immunization is weakened. The argument still remains that the tort process is not an effective mechanism to provide compensation where injury does occur.

Concerns have been raised that no-fault compensation programmes can distort the public's perception of vaccine safety and undermine confidence in immunization

Experts in many jurisdictions have raised concerns that the very existence of a compensation programme for vaccine-related injuries could undermine the public's confidence in immunization (see for example Offit 2008a, Offit 2008b). This concern is amplified in jurisdictions that allow for compensation in cases of injury where there is a high degree of scientific uncertainty surrounding the causal link between immunization and injuries. Critics have pointed to the publicity generated by American no-fault cases that forwarded claims that childhood vaccines are linked to autism. Despite these concerns, there is no published evidence that no-fault compensation programmes have impacted immunization uptake. On the contrary, one could argue that in the most recent public controversy over the purported linkages between vaccines and autism, the lengthy public omnibus hearings held in the United States' National Vaccine Injury Compensation Program have reassured the public first that there is no evidence supporting the vaccine-autism theory and that the issue was truly vetted and rejected.

Low priority

While the ethical case to implement such a programme is clear, there are several other policy priorities related to immunization that have both a national scale and significance. Consultation with experts suggests that bolstering and increasing the capacity and funding for the National Immunization Strategy, including

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the creation of a vaccine registry, implementing a national barcode system, ensuring continued access to new vaccines, and other issues related to barriers to licensing of novel vaccine technologies, especially new adjuvants, would all trump the formation of a coherent national policy to redress vaccine injuries. However, many experts see a no-fault compensation programme as a necessary feature of a comprehensive national vaccine safety strategy (Health Canada, 2001).

Costs

In conjunction with the discussion above, concerns over costs have been cited as a key barrier to launching a national programme (Templeman-Kluit 2008). An analysis of other jurisdictions shows that the total costs for no-fault programmes are relatively modest and represent a small fraction of overall spending on immunization. Adverse events while extremely rare, have been estimated to occur at a rate of less than 40 per 100,000 doses distributed in Canada and are implicated in approximately 20 (probable) – 34 (possible + probable) cases of serious injury per year and only 3 deaths have been associated with immunization in the period between 1997 and 2004 (Public Health Agency of Canada 2006). Only a portion of these injuries would result in substantial uninsured damages or ongoing costs and a need for compensation.

Experience from other jurisdictions suggests that the predicted number of settlements and the cost of any scheme will depend greatly on eligibility criteria, filing requirements, and the public's knowledge of the programme (See Table 2). New Zealand for example has a vaccine-injury case-load ten times the United States or the United Kingdom, at 21.5 cases per million. The case-load does not appear to depend on the likelihood of receiving a settlement, as the United Kingdom's case load is similar to the United States at 2 per million with a claim success rate in the United Kingdom of between 1–2% (over the past few years) versus the United States' claimant success rate of 72%. However, the number of cases compensated is directly related to the eligibility requirements imposed by each system.

SECTION II: CASE STUDIES

The United States National Vaccine Injury Compensation Program (NVICP)

The United States has historically used a no-fault approach to protect manufacturers from civil litigation concerning injuries associated with government-recommended vaccination. An ad-hoc programme was created in 1976 where the government assumed injury liability for an emergency mass immunization campaign against the feared swine flu pandemic. The government did so in response to manufacturer's refusal to release the vaccine without liability protection (Gaskins 1980).

A more sustained crisis occurred in the United States in the late 1970s and early 1980s when a large number of companies stopped producing children's Diphtheria-Pertussis-Tetanus (DPT) vaccine in response to civil litigation over injuries alleged to be caused by the whole-cell pertussis component. Shortages forced officials to abandon booster shots for children and several whooping cough outbreaks were attributed the disruption in the schedule. One analysis showed that at the height of the liability crisis 40% of pharmaceutical liability claims were related to childhood vaccines while profits from vaccines contributed to less than 15% of all pharmaceutical sales (Sturges 1986).

The American Academy of Pediatrics, vaccine manufacturers, and parents of injured children lobbied for the enactment of a no-fault compensation programme (Ridgway 1999). In 1986, the US Congress passed the *National Childhood Vaccine Injury Act* (Public Law 99-660) which created the *National Vaccine Injury Compensation Program* (NVICP) and a special claims office in the US Court of Federal Claims to adjudicate vaccine injury cases. The Act barred virtually all civil litigation for vaccine-related injury (for cases of compensation over $1000) as an initial measure requiring those injured by vaccines to first bring their cases before the NVICP. It also raised the plaintiff's burden to litigate cases based on provider's "failure to warn" of adverse events (Shah 2010). So long as the injuries sustained were presumed to be unavoidable and the manufacturers complied with FDA requirements for product labelling (directions for use and sufficient warnings), manufacturers were shielded from injury liability (Shah 2010). This effectively blocked the most popular legal arguments in vaccine injury cases and made successful civil litigation less feasible and a less appealing option for injured parties (Neraas 1988).

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Table 2. Overview of no-fault compensation programmes for vaccine-related injuries: four case studies. Data capture from programme inception until 2009

Country (Year Implemented)	QUE (1988) Compensation for Victims of Vaccination Program	UK (1977) Vaccine Damages Payments Unit, Department for Work and Pensions	US (1988) United States National Vaccine Injury Compensation Program	NZ (2005) Accident Compensation Corporation
Civil Litigation for vaccine-related injuries	No restrictions	No restrictions	Restricted civil litigation. Must first proceed through Vaccine Court	Civil litigation for treatment injuries is statute-barred
Total cases adjudicated since programme inception (average per annum)	99 (4.5)	5,542 (129)	13,162*(709) *includes 5,605 autism cases	344 (86)
Average annual case load (per million)	(since 1988) 0.7	(since 1999) 2.11	(since 1999) 2.15	(since 2003) 21.5
Average # of awards per year per million	0.2 (1.3/7)	0.05 (3/61)	0.3 (21/330)	11 (42.5/4)
Eligibility Criteria				
Vaccines Covered	Any vaccine targeting a vaccine-preventable disease listed in the Public Health Act, e.g. diphtheria	Specific vaccines listed in the regulations of the *Vaccine Damages Payments Act* (largely restricted to those given to <18yrs)	Specific vaccines listed in *Vaccine Injury Table* (statutory) maintained by Health and Human Services, e.g., polio vaccines	Any vaccine given by a recognised health professional in New Zealand
Filing Deadlines	3 years after death or onset of symptoms	Children >2 but 6 years after immunization or before their 21st birthday	2 years after death; 3 years after symptom onset	1 year after injury onset
Proof Needed	Balance of Probabilities Determined by Expert Review	Balance of Probabilities Determined by Expert Review	Meets Table of Injuries Criteria Balance of Probabilities (3 Prong Standard to prove causation)	Balance of Probabilities Determined by Expert Review
Type of Injury	Any serious permanent injury	Sole cause of disability; 60% disability	Table injuries or proven injuries	Any demonstrated injury leading to damages
Causality Assessment Processes	3 – Member Expert Panel Adjudication (petitioner nominates 1 member)	Expert Review	Table of Injuries; Judicial Review	Expert Review
Compensation	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic, attorney's fees	Medical costs, disability pension, death benefits
Appeals Process	Yes	Yes	Yes	Yes
Number that Appeal	50/99	Approx 5 %	Approx 45 for 2009	Unknown
Legal Representation	Limited (except in appeals)	Limited (except in appeals)	Nearly all claimants	None
Legal Fees	Not routinely Costs awarded in several appeal cases.	None	Legal fees reimbursed for both successful and unsuccessful cases.	None
Evidence for Averted Civil Litigation	Yes-anecdotal	Yes-anecdotal	Yes (published studies, internal government review, anecdotal)	N/A

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The original goals of the United States' system were threefold. First, the advocates of the legislation sought to protect manufacturers and deliverers from civil litigation in order to ensure a reliable supply of vaccines for national programmes. Second, the programme was intended to compensate those injured from vaccine-related injuries in a fair and efficient manner. Third, the programme was enacted to protect the integrity of government-sponsored immunization programmes, maintaining public confidence in vaccines and government agencies (Gokiewicz 2008).

Eligibility rules and administration

The Vaccine Court, the popular name for the Office of the Special Masters (OSM), was created as an adjunct to the US Court of Federal claims. The OSM coordinates the NVICP activities in cooperation with two other government agencies: the Secretary of Health and Human Services (HHS), who serves as the defendant in the injury cases, and the Department of Justice (DOJ), who provides legal representation to the Secretary. The special masters of the OSM adjudicate each case, acting as trial judges. There is an appeals process which proceeds first to a judge of the US Court of Federal Claims, and then to the Court of Appeals for the Federal Circuit (Court of Appeals), and finally to the US Supreme Court.

Unlike administrative-style no-fault compensation programmes, in the US judicial approach almost all claimants have legal representation. The hearing process is similar to civil litigation in that evidence is heard from both sides and expert testimony is crucial for a successful case. Claimant's legal costs are reimbursed if substantiated and deemed reasonable regardless of the judgment, if the special master finds a good faith, reasonable basis for the claim (United States Court of Federal Claims 2011, 126). Once a petitioner's claim is accepted as compensable, the file is contracted to a disability life-planner who assesses the scope and life-long costs of the injuries sustained. The life-planner then calculates a settlement which is paid out as an annuity to the person or, in the case of minors, to their guardians.

Claim adjudication

Similar to other disability entitlement schemes, the NVICP was originally designed around a Table of Injuries, a pre-adjudicated table listing known injuries associated with vaccines (Division of Vaccine Injury Compensation 2006; Golkiewicz 2008). The table defines the window period within which injuries must occur in order to be considered causally-linked to the vaccine and, additionally, the case definitions for each vaccine-associated injury. The table of injuries was created by a committee of experts and was intended to reflect the best scientific evidence related to known adverse events following immunization. To be awarded compensation in a table case, the vaccine received and the injury claimed must meet the definitions and temporal requirements listed on the table. The vaccine must have been administered in the United States, and there cannot be a preponderance of evidence that the condition was due to other factors unrelated to the vaccine. A successful table case does not require a petitioner to establish that the injury was caused by a vaccine in *their particular case*, but rather that their case meets the conditions of a possible causal association, thereby meriting compensation.

The original legislation governing the vaccine injury programme was interpreted by the OSM to allow claimants whose case did not satisfy table criteria (e.g., in cases where petitioners made claims for novel or unexpected injuries associated with a vaccine) to have their petition reviewed on a case-by-case basis to establish causation, or a link between their injury and an immunization, in their particular case. While table cases accounted for most of the vaccine injury claims for the first decade of its existence, after 1995, two trends drove claimants away from table claims to claims based on proving causation (off-table cases) (Division of Vaccine Injury Compensation 2006). First, the only changes or updates to the table in the decades following its formulation were made to restrict eligibility, e.g. narrowing case definitions (Golkiewicz 2008). With an increasingly narrow table of injuries, more and more claimants chose an off-table process that involved a full hearing at the OSM to prove causation; at the same time, the success rate for petitioners dropped markedly and this led to an increase in appeals of OSM decisions to the Court of Appeals (Golkiewicz 2009). Recognising that the original intent of the legislation was, in part, to facilitate citizens' access to compensation for injuries associated with immunization, judges' appeal decisions from the Court of Appeals expanded and codified the process for proving causation in off-table cases, moving

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away from both scientific understandings of probable causation and traditional tort based standards of causation (Green and Grey 2006; Golkiewicz 2008). This made it much easier to prove causation in particular cases under the NVICP than would be possible in traditional civil litigation, making civil litigation much less attractive, despite the more limited damages awarded under the NVICP (punitive damages are eliminated under the NVICP). This in itself fulfills the spirit and intent of the program and its supporting legislation.

The legal standard of causation inscribed in the legislation is a preponderance of evidence, a standard roughly approximating a probability of fifty per cent "plus a feather", or more likely than not, that the vaccine caused the injury. However, unlike civil litigation, while probabilistic evidence from current medical research may be considered by the special master, claimants can meet the standard of probable causation based on reliable **circumstantial evidence** (Green and Grey 2006; Golkiewicz 2008). Thus, scientific notions of *proof of cause*, which generally entail a much higher degree of certainty, have been increasingly trumped by circumstantial evidence in Court of Appeals decisions. The lack of specific direction as to the weighing of evidence (i.e., scientific versus circumstantial) in the statute governing the OSM has created a vacuum that has been largely filled by case precedent through the OSM or in the Court of Appeals.

The case *Althen v. HHS* created a three part sufficiency test to determine whether a vaccine causes an adverse event. These criteria are (1) the existence of a medical theory causally connecting the immunization to the injury; (2) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the injury; and (3) the petitioner can show a proximate temporal relationship between vaccination and injury. The only additional hurdle faced by petitioners is situations where the defendant (in this case the government) argues that the preponderance of evidence suggests that the injury was caused by factors unrelated to the vaccine. The three prong standard can be established using circumstantial rather than "direct, objective conclusive scientific evidence" and causation can be found even in the face of contrary epidemiological evidence.

An assessment of these changes was captured by Gary Golkiewicz, then the Chief Special Master of the programme, who argued that "... we now operate under a table that is very stringent and a causation and fact standard that is far more lenient (Golkiewicz 2008)." To illustrate this, the percentage of successful claims (excluding autism cases) before 1998 was approximately 50% and after 1998 rose to approximately 74% in 2009 (Golkiewicz 2009).

Programme evaluation

Since the programme's inception, 13,198 petitions were filed (as of 10 November, 2009) and 2,372 claims have been successful (including cases that were settled/conceded by the government without going to a hearing). The administrative overhead for the programme is approximately $17 million USD, cost-shared by HHS, the DOJ, and the Court of Federal Claims, or approximately 23% of compensation paid to petitioners for the fiscal year of 2009.[1] Claimant's settlements and awards are paid out of a trust fund which is funded by a special vaccine excise tax of seventy-five cents on every antigen. Revenue from the excise tax for 2009 was $146,670,750 USD. In August of 2009, the trust balance was $3,050,779,483[2] suggesting that the programme is over-funded and the level of excise tax should be revisited. Though the programme was originally designed for children's immunizations, in recent years the number of awards to adults has increased dramatically to over 52% of awards (Golkiewicz 2009). Most of the increase in adult claims is due to claims made for injuries related to the annual flu vaccine.

In his 1999 review of the US programme, Derry Ridgway found that despite some steep barriers to filing claims and accessing appropriate legal representation, many of the original core objectives of the programme were being met. In particular, since its inception, there has been no major supply shortages caused by manufacturers withdrawing from the market due to liability issues (Ridgway 1999, 76) and this finding largely holds true today.

1. Email addressed to JK in response to an information request from the OSM 11/2009.

2. US Treasury, Bureau of Public Debt, August 19, 2009

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While the existence of the NVICP has undoubtedly provided a stable litigation environment for manufacturers, the impact it has had on public confidence in immunization remains more uncertain. During the most recent controversy over vaccine safety involving a broad coalition of parents, activists, and practitioners, who alleged that there is a link between childhood vaccines and the development of autism, the NVICP has served as critical independent civic structure to vet and review this popular theory of harm. While leading scientific agencies, such as the Institute of Medicine, had, by 2003, vetted the epidemiological evidence and various theories connecting autism and routine childhood vaccines, finding no association, the issue retained popular support in various media venues in the United States and created considerable anxiety for parents. Public controversy over the purported link between vaccines and autism led to thousands of petitions filed in the NVICP by parents of autistic children who had undergone routine immunization. The OSM chose to vet the thousands of autism petitions through a series of test cases, the Omnibus Hearings, held between 2007–2009. Overseen by special masters, not vaccine scientists, and through a programme designed to give petitioners a great deal of latitude to prove their claims (and a much lower evidentiary hurdle than civil litigation), the NVICP hearings provided petitioners with a best case scenario to prove their claims. The NVICP also provided a venue for an exhaustive and public review of the science behind the claims being made by autism activists, such as Jenny McCarthy (audio files and complete transcripts of the hearings were made available on the US Court of Federal Claims' website).

During the hearings, the NVICP independently settled a case of neurological injury (described as autism) raising the spectre that the omnibus hearings would find for the petitioners despite a strong scientific consensus discounting the link between autism and vaccines. Paul Offit, a leading vaccine scientist, sharply criticised the evolution of court decisions towards a more permissive settlement environment and pleaded for a more robust scientific definition of *causation* in non-table injury cases (Offit 2008a, 2008b). However, in the end, the OSM's omnibus proceedings conclusively found against the petitioners. The omnibus cases were unsuccessful largely due to the compelling testimony by vaccine experts and scientists at the hearings and the large body of evidence compiled by the Institute of Medicine to examine the purported link.

Offit's analysis did however highlight a series of claims settled where good scientific evidence existed to negate a causal association or where a contested biological theory was given undue credibility in the proceedings (Offit 2008a, 2008b). If the era post 1995 was marked by an imbalance toward a higher standard of scientific causation, recent years have been marked by the reverse trend. Several approaches are being reviewed to rebalance the adjudication process including a half a billion dollar contract with the Institute of Medicine to update research regarding vaccine safety for eight recommended vaccines.[3] This scientific review should assist the government in excluding certain popular biological theories of harm as it did in the US omnibus hearings. Second, the Vaccine Safety Advisory Committee intends to use findings of the research to update the Table of Injuries. The Table has not been expanded to include many adverse-events following immunization (AEFI) currently identified by the Institute of Medicine, including adverse events receiving compensation in other jurisdictions or in earlier US government programmes, e.g., compensating for GBS following influenza immunization as in the 1976 swine-flu immunization campaign.

Given the competing interests between maintaining public confidence in vaccines (supporting robust scientific analysis of risks from vaccines) and providing petitioners with fair, but easy access to compensation and finally in keeping petitioners from crippling manufacturers through civil litigation, it is not surprising that the NVICP will require ongoing fine-tuning, and periodic revision. The most destabilizing force in any no-fault compensation programme remains how high or low the bar should be to determine causation and what level of scientific uncertainty is tenable in settling injury claims (should the system err on the side of scientific certainty or give petitioners the benefits of doubt). If the NVICP has been criticised for erring too much on the side of petitioners, the United Kingdom's Vaccine Damages Payments Unit, discussed in the next section, has been criticized for moving in the opposite direction.

3. Interview with US government official 05/01/08.

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United Kingdom: Vaccine Damages Payments Unit, Pensions, Carers and Disability Services (Department for Work and Pensions)

In the United Kingdom, the ground-work for a no-fault compensation programme for vaccine-related injuries was laid by the 1972 *Royal Commission on Civil Liberty and Compensation for Personal Injury*, led by Lord Pearson. The Commission was created to address public concerns over compensation for personal injuries in the wake of children injured by the drug, thalidomide. While the Pearson commission made a broad set of recommendations to reform civil litigation for injuries associated with medical treatment, more specifically his report advised that children injured by government-recommended immunizations should receive compensation. In 1979, in response to widespread controversy over serious neurological injuries attributed to the pertussis (whopping cough) vaccine, the government implemented Pearson's recommendation in the form of the *Vaccine Damages Payment Scheme* (Robinson 1981). The purpose of the scheme was to "ease the burden" of affected families while recognising that injured children in the United Kingdom would already have access to a range of cradle-to-grave social welfare entitlements. Awards are a singular lump sum that is tax free, currently £120,000 (an amount that has been increased several times since the programme's inception (Owens 2009).

Eligibility rules and administration

The programme's eligibility requirements reflect its focus on ethical concerns over serious damages sustained by children while contributing to a social good. To meet the criteria of having sustained serious or permanent injury, the immunization must be, on the balance of probabilities, *solely* responsible for causing 60% or more disability (originally 80%) in the individual (covered in Section 2 of the General Benefits Regulations). Injuries sustained in-utero or through contact with a recently immunized person are eligible for compensation. This rare situation arises when unprotected bystanders are exposed to infection from viral shedding from the immunization. However, the vaccine cannot have exacerbated an underlying condition (e.g., claims where the injuries were caused by a combination of factors including the immunization and its interaction with non-vaccine related conditions are rejected). Eligible vaccines are listed in the regulations and must have been given in the United Kingdom before a child reaches the age of majority (their eighteenth birthday). In recent years, targeted government-recommended and funded immunizations for groups other than children have led to the following programme expansions: the inclusion of recipients of adult poliomyelitis, rubella, HPV, pandemic influenza A (H1N1), and meningococcal group C.[4]

The Vaccine Damage Payment Scheme is managed by the Department for Works and Pensions, Disability and Carers Service. It has a small administrative staff to process claims, two policy advisors, and a medical director who oversees the medical review of each case. The filing process is fairly straightforward, requiring either the individual or the health care professional to fill in a simple claim form to open a file. The statute of limitations requires that claims are filed before the injured party (or deceased) reaches their twenty-first birthday or six years from the immunization in question. In addition, injury claims are not processed until after a child reaches the age of two, due to difficulties in assessing the degree of permanent disability before that age (Owens 2009). In the event a child under two dies after a vaccination, they are ineligible for compensation under the current programme rules. Similar to any disability scheme, the claim process allows the administrators of the programme to gather any necessary medical documents or files related to the claim, and disability is measured using standardised coding and formulations developed for work-place and general disability claims.

Claim adjudication

The Department's Medical Advisory Service provides expert medical advice across the Department for all medically-related benefits claims, e.g., disability assessments for people claiming a range of disability benefits including Employment Support Allowance, Incapacity Benefit, Disability Living Allowance and Industrial Injuries Disablement Benefit (ATOS 2011). The Medical Advisory Service is currently contracted

4. Joint Interview with 4 UK government officials 14/05/2008.

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to the private company ATOS Health Care, a company specialising in disability assessments for the Department. The consulting medical advisor is instructed to determine if, on the balance of probabilities, the vaccine caused a particular injury (based on a chart review and in some cases a physical examination of the patient) using the following criteria:

- Expert medical opinion exists linking the claimed adverse event and the particular vaccine in question;
- An appropriate temporal relationship exists between the act of vaccinating and the onset of symptoms that led to the injury and the administration of the vaccine;
- No other more probable explanation for the symptoms that led to the injury (including pre-existing conditions that may have contributed to the reaction).[5]

In cases where the background incidence of the disease is similar to immunized populations, the claim is usually rejected, i.e., encephalopathies following immunization.[6] In other words, in cases where there is nearly equal probability that the occurrence was a natural event versus vaccine-related, compensation is denied. In addition, certain popular theories of harm are automatically rejected because extensive review has shown no relationship and there is clear scientific consensus on the issue—for example, cases alleging MMR vaccine causes autism are summarily rejected.[7]

Generally, the Medical Director accepts the solicited opinion from medical advisors and makes a recommendation to the Secretary of State whether or not to accept or deny the claim. The claimants are provided with a reasoned decision to explain why their claim was, or was not, successful. Claimants do have recourse to a three-tiered process of appeal consisting of the following: (1) Tribunal Appeal; (2) Upper Tribunal Appeal; (3) Judicial Review. Approximately five per cent of all rejected claims are appealed, however, only one per cent of these cases heard by the Appeal Tribunal are successful.[8] During the appeals process, the claimant can hire medical experts and legal representation to present new evidence in their case. They also, at any point, have recourse to tradition civil litigation; however, any award in civil litigation will be deducted against the amount awarded under the no-fault scheme.

Claims are usually resolved in three months, although a tribunal appeal can take years. Since 1972, 5,572 claims have been reviewed by the scheme, or approximately 150 per year. Note that, similar to other international schemes, there was a surge in cases at the programme's inception. Nine hundred twenty nine awards have been issued (as of 30 September 2009); however, the vast majority of these claims were related to the DPT vaccine in the late 1970s, and, subsequently, in the past ten years the number of claims (averaging 50-200 claims per year), successful claims (0–5 per year), and total payouts (£0-£500,000) has dropped dramatically. Claims are generally rejected because the expert opinion asserts that there is not a probable link between the injuries and the immunization. For example, recent controversies over a purported link between the Measles-Mumps-Rubella (MMR) vaccine and autism led to a surge in claims of injury. By 2004, there was clear consensus against this biological theory and such claims are now summarily dismissed (Owens 2009).

Programme evaluation

There have been a few evaluations of the effectiveness of the programme. In its early years, there was criticism that the programme's policy to compensate cases 'more likely than not' was compensating more injuries than would meet the strict scientific criteria of causation (Robinson 1981). Robinson's (1981) evaluation argued that the programme was, however, meeting its principal policy goals in providing the just compensation for probable vaccine injuries. He further argued that more restrictive eligibility criteria might satisfy scientists, but would increase the likelihood that the policy goals would not be met. The fears that

5. Joint Interview with 4 UK government officials 14/05/2008.

6. Joint Interview with 4 UK government officials 14/05/2008.

7. Joint Interview with 4 UK government officials 14/05/2008.

8. Joint Interview with 4 UK government officials 14/05/2008.

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lowering the bar to prove causation might falsely attribute injuries to immunization (thereby undermining public confidence in immunization) did not materialize in the years following the programme's implementation (Robinson 1981). Public confidence in immunization rebounded after the programme was implemented and remained very high until the recent controversy over the safety of the MMR vaccine.

However, the interpretation of probable cause by the medical director and consulting medical advisors has become increasingly narrow in the last ten years. This has created a very high bar for claimants and the success rate has dropped accordingly. The drop in successful claims has led to vocal criticism by advocacy groups who claim that the strict interpretation of causality veers from the original goal of the programme to provide just and rapid compensation for those who, on the balance of probabilities, were injured (Owens 2009, Vaccine Risk Awareness Network 2011).

In 1998, a review of the programme led to a lowering of bar for the eligibility requirements with respect to the determination of disability. Previously, claimants had to demonstrate a minimum of 80% disability but this was reduced to 60%. These changes led to a review of 393 rejected claims, of which eighteen decisions were reversed (Owens 2009).[9]

The United Kingdom has implemented an injury compensation programme that is relatively restrictive in both core areas that determine eligibility for compensation: the causality assessment and types of injuries considered. The claimant's injury must satisfy the criteria of at least 60% disability, and this disability must be directly related, through biological mechanisms, to the immunization given. The programme has, historically, met its core objective to provide compensation for those very likely injured while participating in immunization programmes. The programme, also, meets many of the objectives of using a no-fault approach to treatment injury. It provides fair, relatively consistent compensation with a rapid adjudication process. The process is non-adversarial and the civil servants involved in the programme are tasked with aiding and assisting claimants in the process. There is no need for legal representation unless the claimant rejects the judgment. The process is transparent, and the final decision and expert opinion is made available to the claimant who has a limited recourse to an appeals process.

Unlike the approach taken in New Zealand, which will be described in the following section, this is not a high-profile government programme, and there is debate over whether or not publicity for this programme is desirable. It appears that few claimants are aware that the programme exists until they are confronted with a serious injury and health professionals or social services identify their cases as possible claims.

There is currently no process-evaluation that identifies how most claimants are made aware of the programme. The programme is easily found via Google UK (from a search executed in September 2009) using keywords "vaccine damage" (first hit), although other keyword searches such as "vaccine injury" returned only injury lawyers (sponsored websites) and vaccine-critical organizations that focus largely on the United States compensation programme. This may be the reason that many claimants are reportedly dissatisfied with the amount of compensation offered under the scheme (US settlements are ten-fold on average).

The narrowing of the interpretation of probable cause to adhere with strict scientific criteria may satisfy medical professionals, vaccine manufacturers (in the absence of the threat of litigation), however there is an argument that it will ultimately fail to meet the original policy objectives and lead to calls for reform.

New Zealand's Accident Compensation Corporation (ACC)

In New Zealand, no-fault compensation for vaccine-related injuries is part of a comprehensive no-fault approach to medical misfortune (injuries related to medical treatment). The origin of the programme can be traced to the formation of the Accident Compensation Corporation (ACC) in 1974, and the prohibition of civil litigation for personal injury arising from accidents. Vaccine-related injuries only came under the scheme when the government passed legislation in 2005 to include compensation for any injuries suffered while receiving treatment from health professionals (Accident Compensation Corporation 2009). Any unexpected injury that causes any degree of measurable damage is covered under the scheme.

9. The statistics quoted come from supporting documents to Owens (2009).

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Vaccine injury cases represent a tiny fraction of ACC activities overall. Since the introduction of the Treatment Injury legislation on 1 July 2005, the ACC received 27,174 claims for treatment related injuries. Of the 23,260 claims, 15,343 (66%) were accepted and 7,917 (34%) were declined (Accident Compensation Corporation 2009).

Since the inclusion of vaccine-related injuries under the scheme in 2005 (until 2009), there has been 344 vaccine-related injury claims filed and 170 accepted for compensation. The principle reasons for declining claims were, in order of frequency:

- 113 no compensable injury;
- 41 the injury was an ordinary consequence of treatment;
- 14 no causal link between the immunization and injury (Accident Compensation Corporation 2009).

Eligibility rules and administration

The injury claim process must be supported by a registered medical professional and the two required forms for filing a claim are often sufficient for the medical officer to assess the causal relationship between the injury and the vaccine. The ACC does however collect further information when required, i.e. extensive clinical records, reports from registered health professionals, and, in complicated claims, external clinical advice. Medical experts on staff and consultant experts assess whether the claimant should receive compensation. The assessment of causation follows the general ACC protocols and relies heavily on internal review of the likely cause of injury. Of the 344 decided claims, external expert advice was sought only in twelve claims, and the median costs of soliciting expertise in these more complex cases was NZ $788 dollars (Accident Compensation Corporation 2009). If a claim is declined, the petitioner can appeal to the Disputes Resolutions Services, an independent review agency. Claims are rapidly processed and typical claim resolution for the ACC in general is measured in weeks (Bismark and Paterson 2006).

Uniquely, New Zealand allows payout for publicly-insured medical costs. If the injured seeks treatment from a private provider the fees are reimbursed even in cases where the treatment would have been covered under the public system. This allows successful claimants to access a range of privately offered services that frequently translate into more rapid access to treatment than might be expected in the publicly funded system. Since the programme's eligibility requirements regarding the severity of the injury are broad, the payouts are relatively small when compared with other jurisdictions, and the compensated injuries, relatively minor (payouts generally range from a few hundred dollars to several thousand dollars. If a claim is accepted, compensation can include any or all of the following costs:

- Treatment costs
- Compensation for salary or wages lost because of the injury
- Domestic help, such as home help or childcare
- Travel costs, such as to and from treatment
- Equipment, such as crutches, wheelchairs and visual aids
- Home improvements to accommodate the injury such as rails or wheelchair ramps

Programme evaluation

While there has been no specific study published evaluating the vaccine-injury component of the New Zealand ACC, there are several studies evaluating the effectiveness of no-fault compensation approaches to treatment injury (Bismark 2006, Studdert 2001). The ACC has met its goal to provide fast and arguably fair compensation to those who qualify. A review of vaccine related injury claims shows that most injuries compensated through the ACC have been relatively minor, with compensation in the thousands of dollars rather than hundreds of thousands and millions in other jurisdictions. Several serious cases of neurological injury following immunization have received compensation under the scheme. New Zealand's unusually high claim rate (indexed to population) reflects its relatively permissive definition of injury and the highly

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public role the ACC plays in New Zealand public policy. Research on the ACC suggests that unlike most jurisdictions, most New Zealanders are aware that compensation is available for unexpected injuries related to medical treatment, including immunization. This suggests that the key barriers in other jurisdictions to filing claims and meeting eligibility criteria are absent in the New Zealand model (see Table 2).

As a model, the New Zealand approach to compensating relatively minor injuries works well in the context of a larger bureaucracy created to redress treatment injuries, however it would be difficult to construct a programme based on this model in Canada. It does, however, provide an important baseline for the scope and costs of a system with extremely low barriers for receiving compensation.

Quebec's Compensation for Victims of Vaccination Program

In Canada, despite discussions in Manitoba, Saskatchewan, and Ontario, only the Quebec government has instituted a programme to compensate those injured from immunization. The Quebec programme (CVVP—Compensation for Victims of Vaccination Program) was created to respond to a failed lawsuit mounted by Jacques Lapierre, the father of Nathalie Lapierre, a child who suffered from viral encephalitis after a measles vaccination (*Lapierre v. A.G. 1985*). Though the immunization took place in 1972, when the child was five, the case was not resolved until it came to the Supreme Court of Canada in 1985. During the process of litigation, the Superior Court of Quebec found against the government, noting that while there was no-fault involved in the case, there was an undisputed compensable harm caused by a government-recommended immunization. Part of the decision related to the judge's assertion that vaccinating was not strictly voluntary in Quebec due to government-sponsored moral pressure to comply with recommendations to vaccinate to protect not only the individual but also the community from threats from preventable infectious disease (Ministère de la Santé et des Services Sociaux Québec 2011). This ruling was over-turned by the Supreme Court of Canada. While recognizing the inherent justice of awarding a settlement to the Lapierre family, the Supreme Court of Canada maintained that Quebec law did not allow for a settlement where no fault could be assigned and the family's attempt for legal redress failed.

Responding to the Lapierre case, the Quebec government passed amendments to the Public Health act to create a no-fault programme for vaccine-related injuries (R.S.Q., chapter S-2.2, Division III (70-78)). The programme is run by the Office of Public Health, under the Ministère de la Santé et des Services Sociaux Québec (the agency that determines cause), the Société de l'assurance automobile du Québec (the agency that determines the awards according to the *Automobile Insurance Act*), and the Tribunal Administratif du Québec (adjudicates appeals). All vaccines against diseases listed in the *Conditions Respecting Compensation for Victims of Vaccination* are included in the no-fault compensation Programme (a section of the Public Health Act, regulation under the R.Q. C. S-2.2, R.1.)

Eligibility rules and administration

In order to qualify for compensation, the vaccine-preventable disease (as opposed to a specific vaccine itself) must be listed in the regulations, and the vaccine must have been given in Quebec. The victim must have sustained, "Severe permanent damage, physical or mental, including death" (Turmel 2010) and the claim must be filed within 3 years of the immunization or the apparent onset of injury or death. There must be a *probable* causal link between the immunization and the injury.

Claim adjudication

The Ministry requires the individual to fill out a claim form and a medical document release form that allows the office to collate a full set of medical records. In addition, claimants are required to have a physician fill out a claim form on their behalf. Currently, the injured party must request a paper copy of all forms from the Ministry—no electronic copies are available, although, there are plans to make the forms more accessible.[10]

Claims are adjudicated by a medical committee or panel comprised of an expert chosen by the Ministry of Health and Social Services, the claimant, and a mutually agreed upon chair. Normally, the claimant's

10. Interview with Quebec government expert 18/04/2008. See also the programme's website (Ministère Santé et des Services Sociaux Québec 2011).

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appointee is provided with a list of possible chairs from the government's appointee, thus in practice, both the chair of the committee, and the government's appointee are recommended by the Ministry.[11] Committee members are appointed by the Ministry of Health and Social Services and are usually drawn from a small group of experts in relevant fields such as vaccinology, immunology, and paediatric neurology.[12]

Once a chair is chosen, the committee is provided with the claimants' medical documents and directions regarding the adjudication procedures. The committee is tasked with determining, on the balance of probabilities, whether or not the injuries claimed could be attributable to the immunization (Turmel 2010). The committee members can request additional expert opinions and can, and often do, interview or examine the claimant. The committee members are responsible for reviewing the medical records and any relevant medical literature, participating in both teleconferences and face-to-face committee meetings that can include the claimant, and, finally, contributing to and reviewing the draft consensus report. Once the committee has reviewed the documents, a meeting is arranged in the presence of the claimant; the chair moderates the discussion until a majority consensus is reached regarding the cause of the injuries, with respect to the immunization. The stated purpose of the meetings is to both understand the cause of the injury and to give the claimant a reasoned explanation of what happened. The chair of the committee then writes a report that explicitly addresses the probable cause of the injury and its relation to immunization and, also, the extent or degree of permanent injury experienced by the claimant. The chair's report must reflect the consensus of at least two of the three committee members. If one member dissents, the dissenter is required to file a separate report reflecting his or her opinion regarding both causation and the degree of injury (Turmel 2010). These reports are sent to the Minister of Health who ultimately decides if the case is compensable or not—although the Minister has never over-ridden the recommendations of the committee (Ministère Santé et des Services Sociaux Québec 2011).

If a claimant is successful, their case is forwarded to the Services aux Accidentés du Québec (SAAQ), the agency that oversees no-fault compensation for motor-vehicle injuries. Compensation is determined using the criteria specified under the *Automobile Insurance Act*. The determination of compensation for vaccine injuries follows the same protocols as those for motor vehicle accidents using actuarial tables of earning potential and medical costs and the SAAQ coordinates services for rehabilitation (Société de l'assurance automobile du Québec 2011).[13] The compensation provided under the Quebec programme is comprehensive and includes compensation that takes into consideration the full impact of the injuries on a person's life (corporal damages). It includes lost wages, rehabilitation services, domestic and personal services and uninsured medical costs. Payments are generally calculated in the form of an annuity and are indexed to inflation.[14]

Once a decision has been made whether or not to compensate, the claimant is officially informed and given the option of accepting the decision, or they have the right to file an appeal within 60 days to the Tribunal Administratif du Québec (TAQ), an arms-length agency responsible for adjudicating appeals of administrative decisions of the government. The TAQ has the power to over-rule decisions made by the committee.[15] Appeals can be based on the claimant disputing the reasoned judgment regarding the cause of the injury or can argue that their injuries are not adequately represented in the decision. As of October 2010, 55 of the 109 cases adjudicated by the medical tribunal were appealed to the TAQ (Turmel 2010), either to reopen the causality assessment or to appeal the settlement amount awarded.

The TAQ appeal process can consist of a conciliation meeting or a formal tribunal hearing. At a formal tribunal hearing, typically, two administrative judges (usually a lawyer and physician) preside over the case and make a final written judgment. There is no higher administrative body to appeal decisions of the TAQ. The process for the appeal resembles a typical administrative court proceeding where both the claimant and

11. Interview with Quebec government expert 18/04/2008, petitioner's medical committee member 29/07/2008.

12. Interview with Quebec government expert 12/02/2008.

13. Interview with Quebec SAAQ government expert 12/02/2008.

14. Interview with Quebec SAAQ government expert 12/2/2008.

15. Interview with Quebec government expert 18/04/2008.

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government have representation, can call witnesses, and submit evidence for review. Cases take several years from filing the appeal to be heard and can take a significant number of days in court to resolve. TAQ-level appeals of medical committee decisions are usually unsuccessful leaving the claimant to pay legal and expert witness fees. While claimants can proceed without a lawyer, they can also choose to hire representation or apply for legal aid for the TAQ hearing. While lawyer or expert fees are not normally reimbursable under the TAQ proceedings, there have been two successful appeals for the court to pay expert costs of the claimants. When the burden of proof falls on the claimant, the judges reasoned that it was only fair that reasonable costs be recovered to argue the case.The co-appointed medical committee adopted by Quebec is unique in several ways. It provides the claimants with the opportunity to self-appoint a medical professional to act on their behalf in the deliberations over causation and over the extent of their injuries. Though the purpose of the adjudication is to determine if there is a causal link between the stated injuries and the immunization, this system provides a role for an attending physician or someone with first-hand knowledge of the case, regardless of their expertise in the science of vaccine injuries, paediatric neurology, immunology or vaccinology. However, the claimant's physician does not function as an advocate for the claimant. The directive to all committee members is to review the probable cause of the injury and assess whether or not there is a probable causal link between the immunization and the injury in question using the best evidence and science and their knowledge of the case. The presumption is that a fair review of the case with the best evidence serves everyone's interests. Unlike other causality-assessment bodies, such as PHAC's ACCA, the committee does not use a codified approach to determining causation in these cases; committee members judge each case based on their interpretation of scientific literature and their own judgment.

However, the process is structured to be simultaneously less adversarial yet more inclusive of the claimant than other systems. Members of the committee are able to meet directly with the claimant and, in cases where the claim is ultimately rejected, the chair of the committee and the other members often attempt to explain in person their rationale for rejecting the claim. The full report sent to the Ministry is also issued to the claimant and claimant's requests for further explanation and information are also entertained by Ministry of Health and Social Services.

Programme evaluation

Since the programme's inception until October 2010 approximately three million dollars has been paid to twenty-seven successful claimants and the total programme costs have been reported as three and a half million dollars (Turmel 2010). In the one-year period between April 2006 and March 2007, $126,487.29 was paid to claimants and the total expenses related to the Programme added up to $160,530.41 (compensation, administration costs, payments to physicians and experts and other expenses).[16] The total percentage of administrative costs to settlement pay-outs was 27%. Expert committee members are paid approximately $800 per case. Administrative fees by SAAQ to oversee any awards cost approximately $1600 per case in 2007–08. In a one year sample, the average time between the injury claim and settlement was approximately one year, although claims have been settled in as little as one month to over ten years if the case goes to a tribunal appeal. As of October 2010, a total of 109 cases had been evaluated by a medical committee. Twenty-seven (25%) of these received compensation (Turmel 2010).

There has not been a systematic evaluation of the CVVP, however, it has largely fulfilled its original mandate to compensate cases of serious vaccine injury where the link between the vaccine and injury is uncontested by a medical committee (a committee of peers). Each claimant that has been compensated under the programme would have had no realistic recourse to civil litigation for compensation for their injuries. Victims of vaccine-related injuries receive monetary and non-pecuniary supports identical to automobile accident victims and, in the spirit of no-fault, the awards are more consistent and proportionate to injury than awards for medical malpractice in civil litigation, although some experts have argued that the awards are too modest and there has not been an evaluation of claimant experiences with the programme.

16. Follow up email correspondence to JF Letourneau (in French) from Interview with Quebec government expert 18/4/2008.

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Few Quebeckers are likely aware of the programme, and, thus, it is unlikely that the programme has had any direct impact, either positive or negative, on attitudes toward immunization or compliance to recommended immunizations. Having a process to adjudicate vaccine injuries has likely stemmed public controversies over vaccine injury since the rare instances of severe injury, as in the Lapierre case, are now compensated. However, since the TAQ process was put into place, 55 or approximately half of all committee cases were appealed for either disputes over the causality assessment or the determination of the degree of injury related to immunization.

SECTION III: RECOMMENDATIONS

Policy options

Vaccine-related injuries are rare, frequently unavoidable, and require highly specalised expertise to assess the causal relationship between a particular injury and immunization. Despite divergent approaches to compensation and differing eligibility criteria, the number of serious injury claims in three of the four jurisdications studied fell within the expected range of less than one to two serious adverse events per million, with less half of these injuries justifying compensation (Table 2). New Zealand's claim rates (ten times the next highest claim rate) illustrate the dramatic difference in policy objectives and progamme scope between New Zealand's programme and the three other jurisdictions examined. New Zealand's programme is part of a comprehensive accident and disabities scheme that provides compensation for any unexpected treatment injury, at the same time, barring all civil litigation for medical misfortune, while the three other jurisdictions approach vaccine-related injuries as ethically distinct from other treatment injuries. These three programme's restitutive approach hinges on the idea that vaccines (unlike other medical procedures) provide critical benefits to society beyond an individual's protection and cannot be freely refused by citizens in most cases; thus, when citizen's are seriously injured from participating in these programmes there is an ethical imperative to compensate them for these injuries.

The case-load of the jurisdictions studied, and the number of awards issued, indicates that the systems are working to compensate those likely to be seriously injured by immunization.

A review of the problems arising from programmes in other jurisdictions suggests that any no-fault compensation scheme will benefit greatly from the following design features:

1. Clear and internally consistent programme objectives;
2. The ability to resolve claims in a timely fashion;
3. Consistent adjudication of claims (i.e., the same type of claim receives the same type of compensation);
4. Perceived independence or arms-length structure from agencies promoting immunization;
5. Where possible the claim process is structured so that claimants can avoid the costs and expense of legal representation;
    a. Have a codified process to determine causation;
    b. Maintain sufficient expert capacity to draw upon to determine causation in complex/novel types of injury cases or during a the release of a novel vaccine;
    c. Designed such that *access* to the programme is facilitated by medical rather than legal representation;
6. Fair statutes of limitation (take into consideration the fact that, due to the rarity of vaccine-related injuries, it may take some time before a link between an injury and immunization is postulated);
7. Transparent & accountable to the public (communications capacity is critical and a communication strategy is highly desirable);
8. Cross-linkages with scientific agencies to assess novel theories of harm.

Each of these design features will be discussed in turn.

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Determining the core policy objectives

The rationale for implemeting no-fault compensation programmes varies across jurisidictions and chiefly includes:

- Providing just compensation for those who may have been injured by a vaccine (usually determined by a preponderance of evidence and no other reasonable cause for injuries);
- Providing reasonable liability protection to encourage the development of novel immunization technologies (increasingly a requirement for the release of new vaccines in emergency situations);
- Ensuring uptake of recommended immunizations and maintaining public confidence in immunization;
- Improving injury surveillance potentially identifying vulnerable subpopulations or predictable sources of injury (New Zealand only).

As stated earlier, the common core objective for most no-fault compensation programmes is to provide just, timely, and proportionate compensation to those whose injuries can be credibly associated with an immunization. Despite differences in its application, in all jurisidictions this core programme objective has been successfully met. In the four jurisdictions studied, the average time to process claims is generally superior to civil litigation (measured in months to years versus greater than five years for most civil litigation). In most jurisdictions, compensation schemes only provide for *uninsured* costs and losses. The focus is on providing for the unmet needs of those injured and, thus settlements take into account existing insurance, disability entitlements, and other monetary and non-monetary supports. Unlike civil litigation, there are no punitive awards since there is no rationale in most injury cases for a deterrent against the manufacturers or deliverers of vaccines, and pain and sufferring awards are either non-existent or modest when compared to jury awards. Because each jurisdiction has a specialised unit for adjudicating injury cases, awards are more consistent than a jury trial and, being based on need, they are more proportionate to the actual injuries sustained.

The success in meeting other programme objectives is less clear. Assessing the impact no-fault programmes have had on manufacturer's civil litigation costs is notoriously difficult, however Rigway's 1999 study and anonymous interviews from leading vaccine manufacturer's legal advisors support the assertion that there have been significant cost savings to manufacturers, particularly in the United States but also notable in Canada. Vaccine innovation and development flourished in the period following the implementation of international no-fault programmes. The programme has allowed legislators to justify statutes that reduce the likelihood of a manufacturer being held liable for unavoidable, rare, and unpredictable vaccine-related injuries. Beyond the cost-savings of reduced litigation, manufacturers have benefited by the fact that the United States NVICP cases cannot set precedent in civil litigation and the US Health and Human Services has a broad policy objective to settle cases without acknowledging a causal association between vaccine and injury. This process acts as a pressure valve to keep likely un-winnable, but equally expensive and image-damaging vaccine-related injury cases, out of the civil litigation system.

Arguably in the United Kingdom and Quebec, indemnification programmes have also reduced the number of un-winnable civil cases filed in the tort system, and reduced the litigation costs for manufacturers. For example, while Quebec has avoided high-profile vaccine injury cases, civil cases have been filed in Ontario and British Columbia, and a high-profile case of injury in Manitoba prompted the Manitoba Law Reform Commission (an independent government agency) to commission a report on the issue (Manitoba Law Reform Commission 2000).

While litigation restrictions have been put in place in both New Zealand and the United States (for different reasons) it is **unclear** that legislated liability protection for manufacturers is necessary in Canada. The existence of a no-fault programme would provide those with injuries recourse that is otherwise unavailable through civil litigation. However, changes to the Canadian litigation environment have made filing cases of injury easier and more feasible, though not necessarily, more winnable. Liability protection that requires the

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injured to first apply to a national no-fault compensation programme before being allowed to proceed to civil litigation adds an additional barrier to filing un-winnable cases and gives citizens the freedom to reject a no-fault settlement in favour of a higher risk civil lawsuit.

Despite the assertion that no-fault compensation programmes have the potential to improve transparency and can help maintain buy-in and trust for government-sponsored immunization programming there is little evidence to support this assertion. In a review of the literature, we found no study examining attitudes towards immunization that identified injury indeminification as a key issue in individual's decision-making regarding immunization (see for example Cooper et al. 2008). On the contrary, it is more likely that any measured rebound in public confidence and immunization uptake in the 1990s was a response to a broad set of policy interventions to restore public trust in immunization (including replacing the whole-cell pertusiss vaccine with a less reactive one). This assertion is supported by the fact that expert informants in every jurisdiction, other than New Zealand, claimed that the general public awareness of these programmes is poor and, therefore it would be difficult to imagine that there could be an impact on individual decision-making surrounding immunization.

In summary, the core objective of a Canadian no-fault compensation programme should be to justly compensate those injured, fully recognising that their injuries were sustained while they were contributing to a public good. There is little evidence to support a policy objective to increase immunization uptake or maintain public confidence in immunization through an indeminification programme and it can be argued that these objectives can be perceived to interefere with the ethical mandate of the programme. Nor is liability protection for manufaturers a key driver in expert advocacy for a Canadian no-fault programme.

That said, experience from other jurisdictions suggests that a no-fault programme for vaccine-related injures would be best supported by a comprehensive and integrated approach to vaccine safety and communications (related to adverse events following immunization). An ideal program would have the capcity to oversee or coordinate the following set of secondary objectives:

To:

I. To identify novel signals of vaccine-related injury and/or biological theories of harm presented by petitioners in a manner complementary to existing passive and active surveillance systems;

II. Liase with national and provincial/territorial AEFI (Adverse Events Following Immunization) experts and public health agencies to coordinate expertise to provide ongoing analysis and evaluation of injuries;

III. To serve as a respository for information regarding AEFI;

IV. To liase with the Canadian Institutes for Health Research and where necessary commission scientific research to examine emerging theories of harm;

V. Communicate decisions to the public (in a transparent, clear, and accessible manner) and to monitor the public understanding of vaccine injury cases and intervene if harm or misrepresentation is detected.

The institution of the core policy objective and the five secondary objectives would greatly reduce the risk of civil litigation for manufacturers.

Elibiligy criteria

Vaccines and types of injuries covered under the programme

Most programmes either include in their supporting legislation or regulations a list of vaccine-preventable diseases or a list of vaccines covered. In ideal cases, there is language in the legislation that allows for the list to be automatically updated when new vaccines are licensed or added to routine immunization schedules (e.g., in the United States all government-insured vaccines are automatically added to the Vaccine-injury Table). To be consistent with the chief objective of the proposed programme, it would make sense to include any immunization recommended by the National Advisory Committee on Immunization as described in the most recent Canadian Immunization Guide (generally published every two years). In the case of emergent

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threats and novel vaccines released under emergency situations, recommendations from the Public Health Agency of Canada for immunization should also trigger an addition of the recommended vaccine to the programme. Typical eligibility restrictions would require that the immunization be licensed in Canada and given by a recognised health professional in Canada. This avoids the programme assuming liability for vaccines not administered in controlled settings and products called vaccines but not recognised by Health Canada as such (i.e., homeopathic vaccines).

Most, but not all, compensation programmes place restrictions on the type and severity of injury that is eligible for compensation. Presumably, some measurable harm must arise from the immunization that exceeds the minor inconvenience of common adverse events following immunization (such as fever that resolves with over-the-counter treatment, sore arms, and/or aches or fatigue that resolve in a few days). In some cases, a minimal hospitalisation associated with acute care and treatment, rather than observation, is a requirement for compensation (actual rather than potential harm). The United Kingdom has one of the steepest eligibility hurdles for compensation, requiring at least 60% permanent disability for any claim. Similarly, Quebec's scheme requires that the injury be both permanent and serious. Conversely, both New Zealand and the United States have liberal definitions of injury that allow, for example, claims for any unanticipated outcome that creates unexpected burden on the claimant, such as unsightly scars requring cosmetic surgery or transient injuries that result in even modest missed wages or medical costs. Given the time and effort required to file claims in the United States, despite their eligibility for compensation, it is not suprising that these types of injuries have not been a major source of claims. On the other hand, in New Zealand, compensation for *any* treatment injury is perceived by the public as an entitlement and is part of a extremely popular accident benefits programme. This accounts for the disproportionately large number of petitions for minor injuries and also the high number of successful claims. Other than in New Zealand, the eligilibity requirements pertaining to the scope of injury does not seem to have had an impact on the number of petitions filed, suggesting that claimants' filing behaviours are somewhat independent of the chances of being deemed disabled enough to merit compensation. However, a high bar for the type of injury compensated, naturally, has an impact on the number of *successful* claims. In the United Kingdom, for example, in a sample of data taken up to May 2008, 91 of the 4,532 cases that met the relatively stringent causality test were rejected because they failed the 60% disability hurdle.[17]

A reasonable compromise would be to limit claims to serious injury where measurable damages have occurred that resulted in uninsured medical, or rehabilitiative costs, or lost wages. A fixed sum of $1000 in uninsured damages, or a fixed minimum percentage of claimant's income, could be used to set minimums for damages claims in order to maintain the spirit of compensating for serious adverse events. In the extremely rare case of death associated with a vaccine, funeral costs should be provided with a standard death benefit of $250,000 (similar to other insurance schemes). Eligiblility requirements for injuries could be determined using minimal hospital stays for acute events and standard insurance assessment scales of transient and permanent disability to index compensation for the range of rehabilitative, supportive, and monetary losses sustained by the victim.

Filing requirements

Another contentious eligibility criteria is the statute of limitations placed on filing claims for vaccine-related injuries. This varies considerably from as little as one year to almost ten years after the vaccination or onset of symptoms of the adverse event. Most schemes allow adults some restricted period of time to apply for compensation for injuries they sustained as minors. In cases where the connection between an injury and immunization can take many years or may only occur after a specialist raises the issue, filing deadlines can also create unfair barriers to accessing compensation. In all cases, a permissive or a long duration for filing claims is confounded by the need for substantial evidence (complete medical records) and expert support for the claim. In countries without centralised health record systems, obtaining records from private practitioners can be extremely difficult. This issue is a concern in Quebec where many filed claims never proceed to adjudication because the claimant fails to produce adequate medical records.[18] These cases are

17. Supporting documents provided during joint interview with 4 UK government officials 14/05/2008.

18. Interview with government official, Quebec's Indemnities for Victims of Immunization Program 18/04/2008.

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not even recorded in official statistics however they were estimated by a government official to be about 50% of all claims originally filed.[19] One possibility would be to ensure that the special master has sufficient powers to subpoena medical records from health care professionals and health care institutions.

Given the above considerations, a statute of limitations of three years from injury onset would be a reasonable compromise, however, disallowances based on this criteria should be carefully monitored and reviewed on an annual basis. A process of appeal to the programme director or medical officer should be allowed in special circumstances. By definition, imposing a statute of limitations alone imposes a rigid eligibility restriction. Given the uncertainty surrounding many adverse events following immunization and the long duration required to substantiate injury claims with scientific evidence, some flexibility is desirable in specific cases (for example where the emergence of robust scientific evidence supporting new categories of adverse events occurs years after a vaccine programme has been implemented).

Causality assessment

A critical component of any vaccine-injury compensation programme is the assessment of the relationship between the immunization and the injury it is claimed to have *caused*. Causality assessment is defined by the WHO as the, "... systematic review of data about an AEFI [adverse event following immunization] case to determine the likelihood of a causal association between the event and the vaccine(s) received" (WHO 2001). Causality assessment for injury compensation cases differs from the WHO's approach in that the focus is on determining causality, in a specific instance, to determine eligibility for compensation, rather than performing population-based surveillance for adverse events following immunization.

In injury cases, there are two distinct parts to a test of causality. First, the injured must establish "general causation", or in other words, they must establish whether or not there is good evidence that the immunization *can* cause this type of injury. Second, the injured must establish *specific* causation, the demonstration that the immunization was, more likely than not, the cause of the injury in their particular case. The meaning of causation varies from scheme to scheme but typically involves establishing:

- A biological theory of harm
- A temporal association between injury and vaccine
- A logical sequence connecting the injury to immunization
- The absence of more probable cause for the injury (specificity of the association)

In some jurisdictions, such as the United Kingdom, the *strength* of the purported association is also taken into account, in other words, establishing causation leans more towards scientific evidence of a probable rather than possible association (see Figure 2 for the steps taken in a WHO causality assessment process).

In the case of vaccines with a long track record, there is often a substantial body of literature and a consensus-opinion related to types of injuries associated with the vaccine. In the case of new vaccines or novel injuries, causality assessment relies

Figure 2. A codified causality assessment process. Extracted from the WHO "Adverse Events Following Immunization (AEFI): Causality Assessment". Available online from http://whqlibdoc.who.int/aide-memoire/a87773_eng.pdf

2. Evaluate and assess factors.

2.1 Is this event known to be related to the vaccine? ***(Consistency of findings, Strength of association.)***

2.2 What is the frequency of occurrence of this adverse event? Very common (>1/10); common (>1/100); uncommon (>1/1000); rare (>1/10 000); very rare (<1/10 000), or not previously reported.

2.3 Are similar events known to occur with other diseases? ***(Specificity of association.)***

2.4 Is this event explainable by the biological properties of the vaccine? ***(Biological plausibility.)***

2.5 Is the vaccination-to-event interval compatible with the event? ***(Temporal relation.)***

2.6 Has the patient had similar symptoms in the past?

2.7 Is there a history of concomitant or preceding drug therapy?

2.8 Is there a history of a concomitant or preceding condition?

2.9 Are there other factors that could affect the occurrence of the event?

3. Determine causality category using WHO criteria

3.1 Is this an unknown event in relation to this vaccine?

3.2 Is this a new event?

3.3 Is there lack of sufficient data to reach a more definite conclusion?

3.4 Would the case benefit from a second review if more data became available?

19. Email correspondence with government official, Quebec's Indemnities for Victims of Immunization Program.

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more heavily on expert's judgment of the plausibility of the association based on observational studies, case reports of injuries, and the validity of any experimental data supporting a causal association.

Depending on the policy objectives, a key decision in developing a no-fault compensation programme is to define the degree of certainty (that the injury is related to immunization) required to be eligible for compensation. In the United Kingdom, to meet the definition of causation requires that the expert determine that it was more probable than not that the vaccine **alone directly caused** the injury. The interpretation of probable is drawn from scientific rather than legal definitions and thus presents a higher burden for claimants in cases where there is scientific uncertainty.

In the United States, meeting the three-prong eligibility test (in the absence of an alternative cause) using circumstantial evidence from the case rather than probabilistic evidence from research is generally sufficient for compensation. While in the context of the legal proceedings, this approach meets the definition of a preponderance of evidence, in practice, the process is closer to establishing a reasonable or possible cause, in scientific terms. The US approach would garner less controversy, and still fulfill its policy objectives, if it relied on scientific and expert opinion to substantiate the three-prong test of causality rather than allowing causation to be established with circumstantial evidence.

However, redeploying a strict (scientific) test of 'more probable than not' would exclude classes of adverse events that have been the focus of civil litigation and government indemnification programmes, such as the aforementioned Guillian-Barré Syndrome (GBS) following influenza immunization. In this case, there is a body of evidence (peer reviewed research) suggesting an association between influenza vaccine and GBS, however, there is some degree of uncertainty among experts about how robust the data supporting this association is (Health Canada 2002, Juurlink et al. 2006). There would be a diversity of expert opinion in deciding cases of GBS following influenza immunization if a strong *scientific* interpretation of *probable cause* were the foundations of an eligibility test. If the causality test was met when *possible* or *reasonable cause* was demonstrated with good scientific evidence, the outcomes would be more consistent.

Other jurisdictions fall along a spectrum between compensating, in cases with less scientific certainty over probable cause, and requiring a strong interpretation of probable cause. Both approaches have attracted criticism. In schemes that have a steep causality test, there are likely true vaccine-related injuries that are not compensated; contrarily, in those with too permissive a standard, there is compensation for injuries that are not likely caused by immunization. In the more restrictive case, the policy objectives to provide just compensation are undermined and more permissive systems risk raising unfounded concerns over vaccine safety.

If the core policy objective is to provide just compensation, then the causation test should err toward the side of compensating when immunization is established as a possible cause of the injury. However, the case should be substantiated with scientific research rather than circumstantial evidence. If a more likely cause is demonstrable in the particular case then the causation test would not be met. This still gives the claimant the benefit of the doubt and puts the burden on experts to bring forward a reasoned counter-explanation for the injury.

This approach provides a more concrete adjudication process than those based on a scientific understanding of cause, which would require a much higher degree of certainty.

Proving causation using a hearing or case review approach

The most common approach to assessing causation is to require the claimant prove both general and specific causation for their case. Most jurisdictions take an administrative or non-adversarial approach when determining both general and specific causation. They frequently rely on reasoned expert opinion solicited solely by the programme's medical director, as in the United Kingdom or New Zealand. Hired consultants, or in-house government experts are guided by the specific criteria used in each programme (i.e., the threshold required to meet eligibility for compensation) and make their decision through a documentary review of the claimant's medical records or in some cases, additional interviews with claimant. In Quebec, the expert review committee includes a member nominated by the claimant who usually has direct clinical

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Table 3. Divergent approaches to the causality test and their policy implications

Reasonable / Possible cause	Probable cause
Low certainty	High Certainty
More successful claims	Fewer successful claims
More claims awarded that may **not** be associated with immunization	More claims denied that **may be** associated with immunization
Weaker agreement with scientific notions of cause	Stronger agreement with scientific notions of cause
Claimants given the benefit of the doubt	Claimants not given the benefit of the doubt
Increased potential for unfounded concerns over vaccine safety	Decreased potential for concerns over vaccine safety

experience with the injured party. In all models examined, the judgment of causation depends on the individual expertise of the review committee members or hired consultant's reasoned opinion.

Only the United States uses an adversarial model as the first process to determine eligibility for compensation. As described in the case study, adversarial processes normally require claimants to argue their case against the government using supporting experts and evidence. To make this system fair, claimants must have access to legal representation and compensation must include legal fees and court costs. While this system still allows compensation without finding legal fault, an adversarial process erodes many of the touted benefits of a no-fault approach to treatment injury. It is more costly, claims take longer to adjudicate, and it pits citizens against government health officials and leading vaccine experts.

A judicial process makes sense in cases where the public would not perceive a government programme to be fair, neutral, or objective in adjudicating claims. This type of criticism has been raised against some administrative systems where the key players involved in deciding injury cases are simultaneously engaged in promoting immunization, have financial ties to vaccine manufacturers, or have professional and financial interests in promoting immunization. Naturally, when claimants have the sense that claims are not being vetted with due process or that there are vested interests in *not* finding injuries associated with immunization, they are unlikely to be satisfied with the explanation for why their claim was rejected and are more likely to appeal the decision.

In Quebec, for example, there is evidence that more than half of all claimants to the system are dissatisfied with the committee decision, as 55 of the 109 medical committee cases were appealed to the independent Tribunal Administratif du Quebec. This occurred despite the fact that claim settlements in Quebec are quite modest, those injured still have access to coverage under Quebec's health and social welfare system, and individuals largely bear the costs of tribunal appeals (which can exceed the average settlement). Tribunal (TAQ) hearings closely approximate the US judicial model; however, judicial appeals have not been successful in contesting causality decisions in Quebec. While claimants may perceive the medical committee process to be systematically biased or unfair, this is not borne out by the appeal decisions issued by TAQ.[20]

Two approaches could be adopted from different no-fault models to ensure the perception of objectivity and fairness in the adjudication process. One possible remedy would be to have an independent overseer (i.e., a special master, rather than a medical expert chair a medical committee or expert panel). Another option (modeled after the United Kingdom), would be to house the programme in an agency responsible for disability or entitlement programmes rather than in an agency responsible for promoting immunizations.

20. This analysis is based on a review of all publicly accessible appeal decisions of the TAQ. In interviews with an anonymous unsuccessful claimant to Quebec's program, and the claimant's lawyer involved in the TAQ appeal, both argued that the medical committee system was biased and unfair and were equally unhappy with the TAQ judgment.

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Streamlined causality test using a table of injuries

A second approach to adjudicating both general causation and specific causation is to use a predetermined table of injuries. Tables of injuries are frequently used in insurance schemes to assess disability entitlements and automobile accident claims. In its broadest application, the claimant would merely have to demonstrate that their case fulfilled the basic table criteria in order to receive compensation. A claim of thrombocytopenia purpura following Measles-Mumps-Rubella immunization would have to meet the case definition of thrombocytopenia (the industry standard is the WHO-Brighton case definitions) demonstrated through their medical records or laboratory findings (see Table 4). The injury must also have occurred within 7–30 days of the MMR immunization. If both conditions are met, the person would have met the causation test for compensation.

While tables require expert assessment of the injury to see that it meets the case definition for the injury, the outcomes based on this process are more predictable than establishing specific causation and less open to appeal.

The following adjudication process would be followed in Table cases:

Step 1. Verify diagnosis, case definition, and temporal association.

Step 2. If both are met, then the claim is accepted, if not the claim is rejected.

Step 3. Determine degree of injury, and calculate settlement.

Since a table of injuries pro-actively defines classes of compensable cases, it requires significant expert input and ongoing review by an appointed inter-disciplinary causality assessment committee.

However, a table approach makes it more feasible to:

- Solicit expert opinion both nationally and internationally;
- To hold extended deliberations;
- To discuss the implications of additions and deletions of eligible injuries;
- Provide an opportunity to commission research relevant to categories of vaccine injury;
- Allow more time to develop communications to explain the benefits versus risks of immunizing to the public.

A system based on a table of injuries has numerous advantages. Structurally, it provides more transparent, consistent, predictable, and rapid assessments of each claim. Essentially, a table codifies a set of compensable associations between specific immunization and injuries. A table of injuries works best with vaccines with a long track record or well-documented injuries associated with immunization versus injuries alleged to be caused by novel vaccines, injuries with complex or vague case definitions, unexpected injuries, or unintuitive biological theories of harm. Thus, any programme will still require a process whereby claimants can request an expert review of their case. However, if the US experience is generalisable, and if claimants can choose between a table process and individual case review, a table will only be as useful as it is perceived

Table 4. Sample table of injuries entry (US Vaccine Injury Table)

Measles, Mumps, and Rubella Vaccines (MMR, MR, M, R)	Adverse Event	Time Interval
	A. Thrombocytopenia purpura	7-30 days
	B. Vaccine-strain measles in an immunodeficient recipient	0-6 months
	C. Any acute complication of sequelae (including death) of above events	n/a

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to be fair, up-to-date, arms-length from competing interests, and provides a lower bar to establish eligibility for compensation.

A table approach may or may not include the stipulation that clearly-documented contradictory findings (for example, evidence of another more likely cause of thrombocytopenia) would cause the claim to be rejected. However, since the claim process is meant to be technocratic and process-driven, government experts would not be tasked with seeking out new evidence or information that would cause the claim to be rejected. In other words, if a claimant met the table criteria, in the absence of any glaring alternative explanation found in the routine review of the medical file, the programme would find in favour of the petitioner.

One risk of using a table of injuries, in combination with a more permissive causation test, is that tabled associations between vaccines and injuries could be perceived as having been *proven* by the public. This could unfairly undermine the public's perception of immunization safety. It might be prudent in such cases to avoid the term causality altogether to make it clear that the eligibility criteria are based on a scientifically possible association and that causality is not necessary implied.

Maintaining the language of scientific uncertainty is equally, if not more, difficult in individually-adjudicated cases because the public generally perceives the causality in these cases to have been proven. This is particularly true in settings where there is a tribunal or judicial hearing of the case. Even in cases where the government settles for policy reasons, the public can misattribute the action as proving that an injury was caused by immunization. In the US Poling case (*Poling v. The Secretary of Health and Human Services*), the government settled a case concerning a severely disabled girl whose underlying metabolic disorder, in conjunction with a febrile reaction to immunization, may have contributed to permanent neurological damage, including symptoms of autism. The government did not concede causation but settled the case because they felt that it would technically meet the causation test for compensation. The press coverage following the settlement alleged that the government had conceded that vaccines *can* cause autism. This reveals the difficulties officials had communicating the difference between settling a case for policy reasons and proving causation.

In summary, the ideal programme would include a Table of Injuries and a list of disallowances designed to address the majority of petitioner's claims. Petitioners should also have access to individual claim adjudication for novel theories of harm or those not addressed by the Table.

Compensation

There are several distinct models for compensating injuries associated with immunization. In the United Kingdom, a country with a cradle-to-grave social safety net, a lump sum is given, primarily, to acknowledge that the harm was sustained in the pursuit of a greater good and, secondarily, to offset the burden of the injury sustained. In Quebec, compensation is determined based on need for uninsured medical treatments, rehabilitation (including education) or lost income. The Quebec model of compensating injuries uses the acturial tables and rules and regulations governing automobile accident victims and makes use of an existing large-scale administrative entity. Similar federal entities involved in determining disability benefits could be harnessed for a no-fault compensation programme in Canada in order to capitalise on the scale and existing capacity of such programmes (which currently deal with tens of thousands of annual claims versus the less than one hundred claims anticipated in a national vaccine-injury compensation programme). The principle guiding compensation should be to provide for demonstrable uninsured costs related to the injury.

Funding options

Most no-fault compensation schemes are relatively small programmes (compared to other entitlement programmes) and are funded by general revenues. In Switzerland and the United States, there is an excise tax placed on all covered vaccines. The advantages of an excise-tax is that it directly funds the compensation for injuries and can be indexed to fund the programme. The difficulty with this approach is setting up a tax scheme appropriately scaled for both novel vaccines and those with a long safety track record and one that is easily modified if, over time, the average annual case loads drops or rises. In the United States, for example, the excise tax system set up at the programme's inception (when the estimated number of serious adverse events was much higher), has resulted in a large reserve fund of the equivalent of approximately 3.3

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billion dollars (September 2010). A criticism of the US funding model is that the excise tax money was restricted to compensation only and cannot be used for overhead, administration or funding research to assist in adjudicating claims.

In Canada, an excise tax could be implemented to earmark funds for a no-fault compensation programme under the *Excise Tax Act* but the actual funds would flow into general revenues. Given the difficulties in setting appropriate tax levels to avoid the kind of surpluses seen in the US system (some surplus is not only desirable but necessary), it will raise the spectre of having money flow from this tax into other government programmes. Since the costs of any excise tax will ultimately be borne by both the federal and provincial/territorial governments (provinces and territories are the principal purchasers of vaccines), this may create tensions if mechanisms to oversee programme expenidtures and some opportunity to index the tax to programme needs are not implemented. If Canada adopts an excise tax, consideration should be given to use the tax to fund all the programmes' objectives and not just the compensation to those injured. The federal government could also simply fund the programme through general revenues, as it has in the past, for special federal vaccine purchasing programmes, such as the Immunization Trust Fund (Keelan, Lazar et al. 2008).

Administrative body

With the exception of Germany, most jurisdictions have approached vaccine indemnificaton as a national isssue because of the scale-efficiencies in adjudicating cases at the national level. In their recommendations for causality assessment, WHO guidelines include setting up a centralised vaccine safety surveillance system that includes post-licesure safety monitoring and causality assessment for reported injuries. Thus the expertise, authority, and responsibility for reviewing injuries falls primarily on federal governments. All of these features suggest a national approach is both warranted and desirable (either a federal programme or a federally-coordinated programme).

While provinces and territories have largely retained jurisdiction over the determination and delivery of public health programmes, in recent years, provinces and territories have signalled that the federal government should play a strong role in coordinating and subsidising immunization programming across the country in the interest of equity and access to new vaccines (Keelan et al. 2008). There are many arguments supporting a strong federal role in a no-fault compensation programme for vaccine-related injuries. The federal government, through its criminal powers, oversees the licensing of drugs and performs safety monitoring and surveillance, is responsible for immunization programmes on aboriginal lands and for military personnel. Through constitutional powers stemming from *peace, order, and good government*, one could argue that the federal government has a duty to ensure the safety of Canadians through timely access to vaccines and thus shares responsbility for the integrity of immunization programmes. In addition, the federal government, through the Public Health Agency of Canada and its various expert advisory committees has the capacity in both expertise (through its federal and F/T/P expert working groups) and administrative strucutures to oversee such a programme.

There is also evidence that the provinces and territories would support a federal programme to address vaccine-related injury indemnification. The National Immunization Strategy was adopted at the 2003 Conference of F/P/T Deputy Ministers of Health (F/P/T Advisory Committee on Population Health and Health Security (ACPHHS) 2003). The objectives of the Strategy were ultimately funded by the federal government through a dedicated trust. The long-term goal of the architects of the National Immunization Strategy was to institute a permanent body charged with implementing a broadly collaborative F/T/P policy process to negotiate comprehensive and harmonized immunization policies across the country. Core components of the strategy included setting national goals and objectives, ensuring collaboration on immunization programme-planning, research, and evaluation, securing the vaccine supply and setting up a national vaccine registry (Keelan et al. 2008). Arguably, the administration and implementation of a no-fault compensation programme falls within the mandate of the NIS.

One option would be to propose a model programme for all jurisdictions. The federal government could use its funding powers to finance provincial and territorial no-fault schemes, for example, funds from the

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Immunization Trust could be ear-marked to support the programme. The strengths of this approach are that the provinces and territories would receive financial support to fill a recognised policy gap. However, this approach would not ensure that all Canadians would have access to the same compensation, and some provinces may choose not to provide compensation at all. Finally, smaller provinces will lack the expert capacity to effectively adjudicate injury cases creating further inequity.

Another option would be to establish, similar to the United States, a special federal administrative court to adjudicate claims under the Department of Justice in collaboration with the Public Health Agency of Canada. Legislation would be required to constitute a federal administrative court with the authority to hear vaccine injury cases, and provinces could be given the opportunity to opt-out and receive financing for their own programme. The United States opted for a judicial model largely because of historical features particular to the United States that are not measurably appropriate for Canada. In addition, there would be steep constitutional barriers to create a federal judicial body to hear vaccine-related injury cases, with the possible exception of vaccines released during a public emergency or pandemic.

Alternatively, the federal government could follow the lead of most international models and create a federal entitlement programme. The legislation could allow for provinces or territories to opt out if they create an equivalent programme. The programme could be co-administered by Service Canada and the Public Health Agency of Canada and include the following components:

- A standing causality assessment committee (responsible for a table of injuries)
- A special master to adjudicate individual claims
- A programme director to manage communications and claims processes
- An administrator to assist claimants with the filing process
- A disability/injury assessor
- Consulting experts to serve on individual review committees

This approach would ensure equitable accesss to compensation across the country, efficient processing of claims, and use of expert and national advisory committees. However, it is highly likely that Quebec would choose not to participate in a national programme.

Periodic review and table of injury updates

A process should be implemented to review tribunal cases to identify injuries of interest related to unexpected novel theories of harm, or a clustering of injury claims related to a specific immunization. An annual audit should be performed to assess the consistency of committee decisions. If individually reviewed claims are reliably being settled in favour of the claimant than the standing committee overseeing the table would consider whether the claim should be included on the table. Conversely, table injuries should be periodically reviewed if there is a significant change in the state of immunization science or technology. Finally, a list of disallowances could be developed to process popular claims where there is a substantial body of evidence to dispute a causal association between vaccines and specific injuries, as in the recent purported vaccine-related autism cases.

Linkages with scientific agencies

The establishment of a no-fault compensation programme will require expertise from, and collaboration with, existing national scientific advisory committees and professional organizations representing both the medical profession and disabled citizens. If there is divergence in decisions over similar cases, or scientific uncertainty that creates ambiguity in assessing certain types of cases, the agency should consider providing funds to CIHR for a Request for a Proposal (RFP) to provide a stronger evidence-base for these decisions. This approach was recently taken by US officials to fund an evidence-based review of vaccine safety for eight routine childhood vaccines.

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Table 5. A comparison of components of the proposed no-fault compensation programmes with those in other jurisdictions.

Country	Proposed National Programme	QUE (1988-)	UK (1977-)	US (1988-)	NZ (2005-)
Core Policy Objective	Provide just compensation for victims of treatment injury	Provide just compensation for victims of treatment injury	Ameliorate burden of vaccine-related injuries sustained in the pursuit of a public good	• Limit civil litigation against manufacturers • Compensate for costs pertaining to vaccine-related injury • Maintain public confidence in immunization	• Provide just compensation for victims of treatment injury • Improve patient safety
Civil Litigation for Vaccine-related injuries	Options: No Restrictions or must proceed first through the programme	No restrictions	No restrictions	Restricted civil litigation allowed: must first proceed through Vaccine court	Civil litigation for medical injuries is statute-barred
Av. Case Load	Est. 0.72-2 per million	(1988-) 0.7 per million	(1999-) 2.11 per million	(1999-) 2.15 per million	(2005-) 21.5 per million
# Awards	Est. 0.2-0.3 per million	0.2 per million (1.3/7)	0.05 per million (3/61)	0.3 per million (21/330)	11 per million (42.5/4)
Compensation	Uninsured medical and rehabilitation costs, and lost wages	Uninsured medical costs, rehabilitation, death benefits	Lump sum £120,000	Annuity for medical costs, lost wages, non-economic, attorney's fees	Medical costs, disability pension, death benefits
Appeals Process	Yes	Yes	Yes	Yes	Yes
Legal Representation	Not required	Limited (except in appeals)	Limited (except in appeals)	Nearly all claimants	None
Legal Fees	None	Not routinely TAQ has awarded court costs in several cases	None	Legal fees reimbursed for both successful and unsuccessful cases	None

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CONCLUSIONS

Canada should implement a national no-fault compensation programme for vaccine-related injuries. The programme's chief objective should be to compensate those who have likely been injured by immunization. Eligibility for compensation would require that the injured received a government-recommended, licensed vaccine given by a recognised health professional in Canada. A reasonable statute of limitations for filing claims of up to 3 years after immunization or onset of symptoms would be implemented, however, a process of appeal would be reserved for extraordinary circumstances. An ideal programme would have at its core a Table of Injuries designed to address the majority of claims filed. The Table injuries should be based on the most up-to-date scientific research and should provide compensation in cases where evidence supports that it was at least scientifically and clinically possible that the injury was caused by immunization and there are no other more probable causes for the injury presented in the medical records. Petitioners should also have recourse to an individual hearing or case review overseen by a special master (see Figure 1). Compensation should be provided based on the principle that all uninsured expenses resulting from the injury would be included in a settlement. A lump sum should be paid in the event of the death of the injured party.

The no-fault compensation programme should be supported by the following:

- A federal bureaucracy to adjudicate claims and compensate injuries including a special master, programme director, part-time medical director, claims processing administrators, and a disability assessor. The Programme Director should also be tasked with overseeing a communication strategy for the programme and coordinating activities between the programme and offices of the National Immunization Strategy, and F/T/P scientific advisory committees and vaccine safety research agencies.
- A standing expert advisory committee to oversee the table of injuries. The core committee membership should include experts in vaccinology, immunology, neurology, pediatrics, public health ethics, health law, and public health policy

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Canada

No-Fault Vaccine Injury Compensation Programs

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Purpose

- Present the Vaccine Task Force with a high-level overview of the current domestic and international context as it relates to Vaccine Injury Compensation regimes

- Solicit VTF perspectives pursuant to this to help inform policy considerations

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Background

- Vaccination is an altruistic measure citizens undertake to help protect not only themselves, but also their communities, and the rest of society from infectious disease

- Regardless of the rigour of vaccine clinical trials and excellence in vaccine administration, a small number of Canadians will experience an adverse event following immunization (AEFI), ranging from mild (e.g. pain at the injection site, fever or dizziness) to more severe (e.g. anaphylaxis and in very rare instances death)

- Serious vaccine injuries that result in long-term disability or death are exceptionally rare (fewer than one for every million doses)

- Reciprocity is the foundation for establishing VIC programs: *"It is fair and reasonable that a community that is protected by a vaccination program accepts responsibility for and provides compensation to those injured by it" (WHO 2011)*

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Introduction

- At the present time, Canada is the only G7 country without a no-fault VIC program with the exception of Quebec's program established in 1988
- The current COVID-19 context presents an opportunity to reconsider this long-standing gap in Canada's vaccination system and Canada's alignment with the global community
- We have a number of specific questions that we would like your views on and hope that these questions will generate a robust discussion of public policy questions that have been with us for a while.
- We will look forward to hearing the Vaccine Task Force's views on potential scoping and framing of a VIC and about how we might strengthen Canada's vaccination landscape.

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Why establishing a VIC program for Canadians has proven difficult…

- The longstanding GoC position has been that P/Ts are better placed to create VIC programs as they are primarily responsible for deciding which vaccines to include within provincial health plans and for the actual delivery of vaccines to the general public

- In past FPT discussions (in the late-1980s, early-2000s and most recently in 2013 as part of the renewal of the National Immunization Strategy), jurisdictions expressed general support for the underlying principles of VIC, but progress has proven elusive

- Since 2013, PTs have not prioritized creating a pan-Canadian VIC program nor signalled interest in revisiting the issue

- While incenting PTs to create VIC programs has previously been on the table, sensitive issues around conditionality and jurisdiction proved challenging:
  - do all P/Ts need to commit to creating a VIC program within a specific timeframe and how similar/equitable do these programs need to be?
  - is there a baseline level of P/T post-market vaccine safety monitoring capacity that needs to be in place to receive funding (and if so, who determines compliance)?
  - should coverage be limited to vaccines administered consistent with National Advisory Committee on Immunization (NACI) guidance?

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Principled and practical reasons why Canada should consider aligning with other countries on VIC at this time…

ATIA - 21(1)(a) ATIA - 21(1)(b)

PRINCIPLED REASONS

Principled and practical reasons why Canada should consider aligning with other countries on VIC at this time… cont.

PRACTICAL REASONS

ATIA - 21(1)(a) ATIA - 21(1)(b)

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Lessons from Quebec

Quebec's Experience

- Quebec's well-established and successful no-fault VIC could serve as the ***baseline for a pan-Canadian regime***; it would be difficult to envisage a new pan-Canadian program with significantly higher or lower eligibility criteria, burden of proof requirements or compensation levels

- Since its creation in 1988, 284 cases (approx. 7.5 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (approx. 1.6 annually) were accepted and another 44 claims were not pursued.

- Over 32 years, Quebec's VIC Program has issued $6.5 million (approx. $250K annually) to successful claimants

- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec has an Administrative Tribunal that reviews the cases; if the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).

- Claims are heard by a three-person medical tribunal and decided by a 2/3 majority opinion. One tribunal member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.

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ATIA - 21(1)(b)

Considerations for a National VIC Program

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Questions for Discussion

1. Would now be a good time to establish a VIC program?
   -- If not now, when would be a good time?
   -- What are the major considerations? (e.g. communications, anti-vaccination movement)

2. Should coverage include pandemic vaccine only, or extend to other HC approved vaccines?

3. Should a national, federally administered VIC program be created or should PTs be supported in creating their own VIC programs?

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The Case for Vaccine Injury Compensation in Canada

ATIA - 19(1)

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Declaration of Conflict of Interest

[redacted]

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History

- Calls for vaccine injury compensation since the 1980s (Canadian Pediatric Society).
- Further assessment of rate of AEFIs resulted in the creation of IMPACT.
- Despite further data suggesting AEFI rate was low, Canada never adopted a national system. Canada is now the only G-7 country that does not have a vaccine injury compensation system.
- Only recommendation of National Immunization Strategy working group that was not adopted.

ATIA - 21(1)(a)

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Our recommendations

[redacted]

ATIA - 21(1)(a)
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Arguments against vaccine injury compensation

WITHHELD / RETENUE

Is(Are) exempted and/or excluded pursuant to section(s)
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21(1)(a)
The head of a government institution may refuse to disclose, if the record came into existence less than twenty years prior to the request, any record requested under this Act that contains (a) advice or recommendations developed by or for a gove
Le responsable d'une institution fédérale peut refuser la communication de documents datés de moins de vingt ans lors de la demande et contenant : a) des avis ou recommandations élaborés par ou pour une institution fédérale ou un ministre

21(1)(b)
The head of a government institution may refuse to disclose, if the record came into existence less than twenty years prior to the request, any record requested under this Act that contains (b) an account of consultations or deliberations in whi
Le responsable d'une institution fédérale peut refuser la communication de documents datés de moins de vingt ans lors de la demande et contenant : b) des comptes rendus de consultations ou délibérations auxquelles ont participé des administrateur

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Landscape Analysis

Jurisdiction	Year	Admin.	Vaccines	Eligible comp.	Types of comp.	Funding
Germany	1961	State	Gov. rec.	Injury beyond normal post-vaccine reaction	Med. & funeral costs, disability pension, non-econ. loss, death benefits, supplemental benefits >6 mo. disability	GR of state govs.
France	1964	Min. of Health	Mandatory	Any injury directly attributable to vaccine	Med. & funeral costs, non-econ. loss, death benefits, loss to relatives	National treasury
Japan	1970	Min. of Health.	Gov. rec.	Disability or death	Med. & funeral costs, disability pension, non-econ. loss, death benefits, bereavement pension	Multiple levels of gov.
Switzer.	1970	Fed. Dept. Home Affairs	Gov. rec.	Serious injury	Lump-sum comp. up to 70,000 Swiss francs	GR of state and federal govs.
Denmark	1972	Danish Pt. Comp. Assoc.	All	Damages above 3,000 DKK	Med. costs. disability pension, death benefits, non-econ. loss, pain and suffering, addit'l expenses and losses less statutory benefits	National treasury
NZ	2005	ACC (crown corp.)	All	Injury beyond normal post-vaccine reaction	Med. costs, disability pension, death benefits, support for dependents, lump-sum for impairment	Specific tax revenue
Sweden	1978	Private drug insurance	All	Injuries listed in FASS or in medical literature	Med. costs, disability pension, non-econ. loss, death benefits, lost wages, pain and suffering, addit'l expenses and losses less statutory benefits	Pharma company contributions
U.K	1979	Dept. Work & Pensions	Gov. rec. in legislation	Injury resulting in >60% permanent disability	Lump sum payment up to GBP 120,000	National fund
Quebec	1988	Min. of Health	Gov. rec. in legislation	Serious injury or death	Med. costs, disability pension, non-econ. loss, rehabilitation, death benefits	Provincial gov.
U.S.	1988	DOJ, Dept. Health,	Gov. rec. in legislation	Any injury likely caused by vaccine	Med. costs, disability pension, lost wages, non-econ. loss, future care costs, death benefits, attorney's fees	Excise tax
Taiwan	1988	Min. of Health	Mandatory	Injuries listed on table of injuries	Med., funeral, illness, impairment costs; disability pension, non-econ. loss, death benefits	Excise tax
Italy	1992	Min. of Health	Mandatory & rec.	Permanent injury or death	Med. costs, disability pension, non-economic loss, death benefits	National treasury
Norway	1995	Min. of Health	Gov. rec.	Damage above 10000 NOK or 15% disability	Med. costs, disability pension, non-econ. loss, death benefits, pain and suffering, addit'l expenses and losses less statutory benefits	Ntl treasury, pharma contributions
Austria	1973	Min. of Social Affairs	All	Severe bodily harm	Med. costs, disability pension, non-econ. loss, death and disability benefits; rehabilitative costs; lump-sum payments for less severe injuries	Gov.
Latvia	2014	Ntl Health Service	All	Damages to life, health; treatment-related expenses	Maximum comp. EUR 142,290 for damage to health or life; med. costs up to EUR 28,460	Contributions from medical institutions
Nepal	2018	Min. of Health	Gov. rec.	Physical losses	Does not specify	Gov.
Vietnam	2016	Dept. Health Rec.	Gov. rec. (NIP)	Disability or death	Disability: equivalent to 30 mos. base salary/calculated based on lost/reduced income w/ formula; expenses prior to death; funeral costs; mental suffering for relatives; earning loss	Gov.
Slovenia	1997	Central gov.	Mandatory	N/A	Med., disability pension & funeral costs	Likely gov.
Hungary	2005	Central gov.	Mandatory	N/A	Med., disability pension & funeral costs	Likely gov.
Luxem.	2000	Min. of Health	Gov. rec.	N/A	N/A	Likely gov.
China	2006	Multiple levels of gov.	Gov. rec.	Severe disability/death directly attributed to vaccine	Province-dependent	Gov. (NIP); pharma (non-NIP)
Finland	1983	Private drug insurance	All	Loss of functional ability for at least 14 days	Unreimbursed med. costs, disability pension, non-econ. loss, death benefits, pain and suffering, additional losses less statutory benefits	Manufacturers' tax
Korea	1995	Korea Advisory Comm. on VIC	Gov. rec. (NIP)	Moderate-severe AEFIs w/ treatment cost >₩300,000	N/A	Gov (NIP); pharms (non-NIP)
Iceland	2001	Icelandic Health	N/A	N/A	N/A	N/A

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How predictable are the number of claims and settlements?

- Despite divergent approaches to compensation, serious claims are roughly fewer than 1-2 claims per million vaccinated, with less than half of these injuries justifying compensation.
- The introduction of new vaccines is associated with a spike in novel claims and injury compensation, but this levels-out fairly quickly.
- The predicted number of settlements and the cost of any program will depend on eligibility criteria, filing requirements, and the public's knowledge of the program.
- The number of cases compensated *is* directly related to the eligibility requirements imposed by each system.

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Likelihood of AEFIs

"...from 2006 to 2018 over 3.7 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 7,370 petitions were adjudicated by the Court, and of those 5,151 were compensated. This means **for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated.**"

US Health Resources and Services Administration, 2020

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Key take-aways from landscape analysis

1. No-fault compensation is the preferred approach to deal with AEFIs globally.
2. Compensation programmes have been proven to be long-standing and adaptive to evolving evidence.
3. Most compensation programmes address uninsured medical costs for serious and permanent injury associated with government recommended vaccines.
4. Most compensation programmes achieve a balance between scientific and policy objectives.
5. Overall, programmes have been successful in meeting their goals.

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Pandemic vaccine injury compensation

- Most programmes incorporate pandemic vaccines by default.
- The U.S. has experimented with emergency measures legislation to cover pandemic vaccines.

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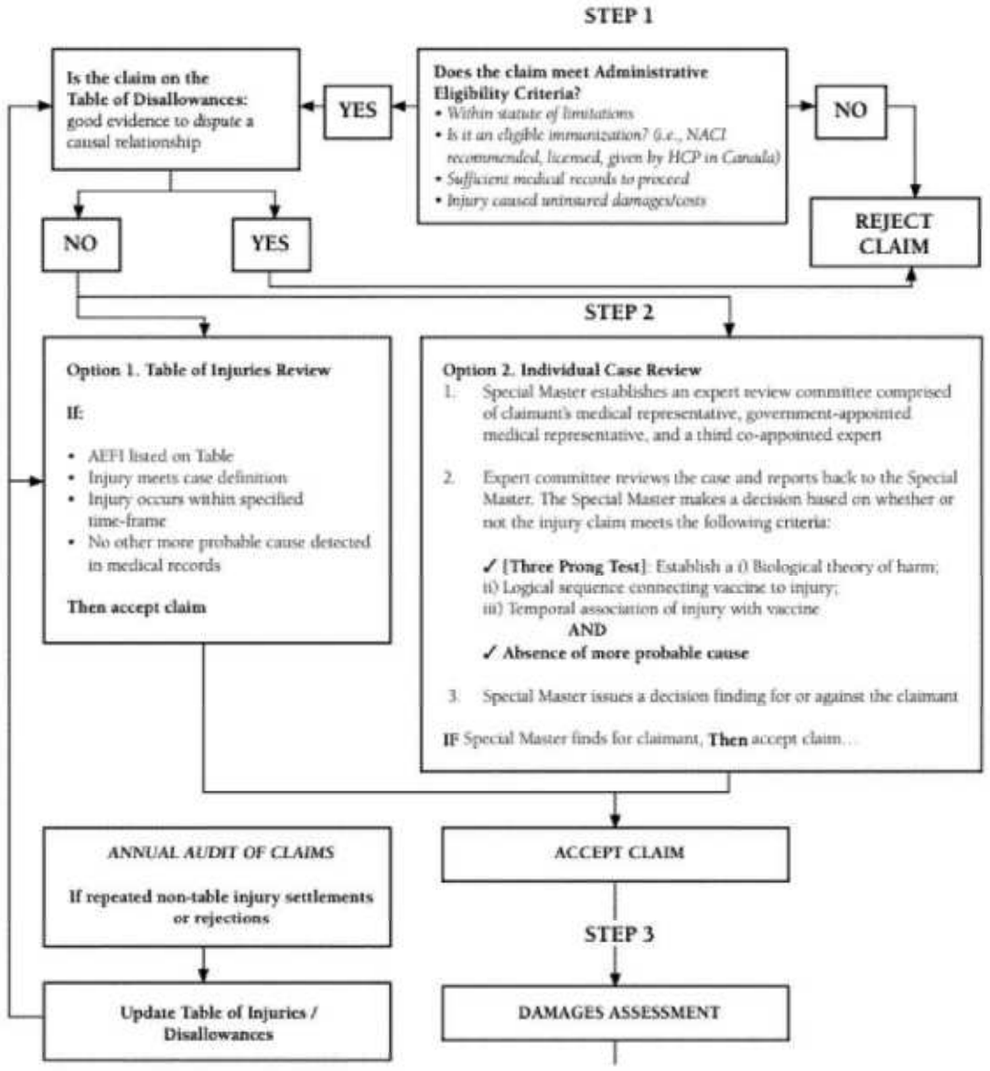
STEP 1
Is the claim on the Table of Disallowances: good evidence to dispute a causal relationship
YES
Does the claim meet Administrative Eligibility Criteria?
• Within statute of limitations
• Is it an eligible immunization? (i.e., NACI recommended, licensed, given by HCP in Canada)
• Sufficient medical records to proceed
• Injury caused uninsured damages/costs
NO
NO
YES
REJECT CLAIM
STEP 2
Option 1. Table of Injuries Review
If:
• AEFI listed on Table
• Injury meets case definition
• Injury occurs within specified time-frame
• No other more probable cause detected in medical records
Then accept claim
Option 2. Individual Case Review
1. Special Master establishes an expert review committee compeised of claimant's medical representative, government-appointed medical representative, and a third co-appointed expert
2. Expert committee reviews the case and reports back to the Special Master. The Special Master makes a decision based on whether or not the injury claim meets the following criteria:
✓ [Three Prong Test]: Establish a i) Biological theory of harm; ii) Logical sequence connecting vaccine to injury; iii) Temporal association of injury with vaccine
AND
✓ Absence of more probable cause
3. Special Master issues a decision finding for or against the claimant
IF Special Master finds for claimant, Then accept claim...
ANNUAL AUDIT OF CLAIMS
If repeated non-table injury settlements or rejections
ACCEPT CLAIM
STEP 3
Update Table of Injuries / Disallowances
DAMAGES ASSESSMENT

[redacted]

[redacted]

[redacted]

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Final words

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Canada

COVID-19 Vaccines
International Context

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COVAX

- No precedence for routine immunization programs, outbreak response at the global level
- UNICEF serves as the supply and procurement agent on behalf of countries and donors including Gavi, the Vaccine Alliance based on recommendations for use by WHO and country governments
- Recipient country governments assume responsibility for the distribution and administration of vaccine; manufacturers are liable and held responsible for the product; all other parties are indemnified
- R&D Blueprint (WHO) for vaccines under development used under EUL/compassionate use

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ACT-Accelerator

- Under the COVAX Facility, self-financing (HIC/UMIC) would use existing vaccine injury compensation programs
- Under the COVAX AMC, countries accessing vaccines with funding support through Gavi under EUL and early scale-up and distribution:
  - Opportunity to leverage experience of WHO?
  - Acceptance of countries – jurisdictional consideration and legal framework?
  - Administration of such a program?
  - Calculation of compensation for countries with varying GNI (determination of the compensation and agreement on the parameters for such)? Funding mechanism?
  - Would this set a precedence (what would be the limits of such a program)?

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September 28, 2020

The Honourable Navdeep Bains, P.C., M.P.

Minister of Innovation, Science and Industry

The Honourable Patty Hajdu P.C., M.P.

Minister of Health

Dear Minister Bains and Minister Hajdu,

We are writing to provide you with an update on the work of the COVID-19 Vaccine Task Force (CVTF), following meetings on September 10th, 17th and 24th. In the course of these meetings, at the request of your departmental officials, we covered a lot of ground including: Canada's involvement in the COVAX facility; the work of [redacted] our recommendation on [redacted] vaccine rollout plans; international Advance Purchase Agreements; and views on how to bolster vaccine confidence.

September 10th Meeting

International Activities – COVAX Facility

On September 10th, Global Affairs Canada (GAC) and Health Canada returned to the CVTF to share information on their international activities relating to the COVAX Facility, the vaccine pillar of the World Health Organization Access to COVID-19 Tools (ACT) Accelerator. [redacted] the aim of the ACT Accelerator is to expedite the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. Global Affairs Canada reiterated that Canada is expected to play a multilateral role to support countries that cannot afford access to vaccines and that a country's ability to pay must not be a barrier to access safe and effective COVID-19 vaccines.

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During their presentation, Health Canada highlighted the different pathways to secure access to COVID-19 vaccines through COVAX. It was noted that doses will be distributed in real time and that all participants in COVAX would receive doses to cover a minimum of three percent of their target populations as soon as a vaccine becomes available. Originally, the COVAX goal was to procure 2 billion doses by the end of 2021.

The Task Force was informed that, similar to the Canadian portfolio, the COVAX portfolio of vaccine candidates is diverse, from technology, geographic and manufacturing perspectives. Health Canada indicated that that there is commitment to grow this portfolio and that other candidates are being reviewed to target: new antigens; vaccines with trials in special needs populations; and expanding geographic spread.

[redacted]

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VIDO-InterVac

The Task Force was very interested to hear from Dr. Volker Gerdts, Director and CEO of VIDO-InterVac. The purpose of the presentation was for the Task Force to receive a general overview of the organization.

This research organization is focused on infectious disease research and vaccine development and is situated on the University of Saskatchewan campus. We were impressed by the facilities at VIDO-InterVac, which has one of the largest Level III biocontainment facilities in the world. As would be expected, with their experience in animal model research, this organization is highly sought after by pharmaceutical and academic institutions from all over the world.

Dr. Gerdts indicated that VIDO-Intervac had received significant funding from various sources including the Canadian Institutes of Health Research, the Government of Saskatchewan and others, totalling more than $40 million dollars. [redacted]

Dr. Gerdts highlighted that VIDO-InterVac was the first Canadian organization (in collaboration with Sunnybrook and the National Microbiology Lab) to isolate SARS-CoV-2 from a patient sample. They were also the first in Canada to establish ferret and hamster in vivo experimental models for COVID-19.

[redacted]

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[redacted]

September 17th Meeting

Vaccine Rollout Plans

As we have noted before, the CVTF has been seized with the need for urgency in responding to the pandemic – in securing doses of COVID-19 vaccine, and in ensuring a robust rollout plan for immunization. On September 17th, PHAC provided important details on the coordinated plan for the rollout of COVID-19 vaccines in Canada. PHAC indicated that they viewed the COVID-19 pandemic as an unprecedented situation in public health and that they were working to be ready for all potential scenarios, with the ultimate goal of being ready to immunize by January 2021.

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We were reassured to hear this and to learn about Canada's COVID-19 Immunization Strategy: From Vaccine Development to Delivery, a comprehensive and overarching piece that sets out objectives, roles and responsibilities, governance and milestones.

We support PHAC's view that Canada's leadership needs to be unified in a way that is unprecedented. They indicated that work is underway to develop a federal-provincial-territorial (FPT) framework agreement of principles and objectives to ensure cohesion. We also support this as a strong signal to Canadians that different levels of government are working together and in the same direction.

PHAC elaborated on a number of elements in the COVID-19 Immunization Strategy that the Task Force had considered previously including that:

- Vaccine confidence underpins success. A strategy is being developed to reach target groups, and to create a space for dialogue and partnership with Canadians. It aims to provide accurate information and combat misinformation;
- Vaccine allocation requires accessing equipment and logistical planning for cold chain capacity, ultra-cold chain storage, and capacity in the supply chain;
- Vaccine delivery is built on the systems in place for annual influenza vaccine programs, with additional elements to address the specificities for COVID-19 vaccines;
- Vaccine administration is an important FPT activity and will be critical in preparing the Provinces and Territories (PTs) and in bolstering the PT supplies needed for rollout (i.e., needles, syringes, PPE); and
- Vaccine safety, coverage and effectiveness has a focus on tracking, reporting, analyzing, and adjusting. This requires connected data systems and the Government of Canada is working with the PTs to get that in place. Once operating, this system will represent a major contribution to the country and a legacy piece.

PHAC requested that we provide advice on three main areas of Canada's COVID-19 Immunization Strategy:

[redacted]

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[redacted]

The CVTF has considered aspects of these questions at previous meetings. We appreciated the opportunity to discuss these questions at length and to crystalize some of our previous thoughts into recommendations.

[redacted]

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[redacted]

September 24th Meeting

Vaccine Injury Compensation

To continue our discussion on vaccine injury compensation (VIC), we hosted several guests to provide us with a comprehensive overview of the issues surrounding the implementation of a VIC program in Canada. Kim Elmslie, Arlene King, and Heather Deehan joined us from the PHAC, along with [redacted] from the University

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of Ottawa and [redacted] and University of Toronto School of Public Health.

PHAC opened the discussion with a presentation that outlined the Canadian landscape. We were concerned to hear that Canada is the only G7 country without a no-fault VIC program (with the exception of Quebec's program, established in 1988). [redacted] broadened the discussion with a multilateral outline of 26 other jurisdictions around the world with established VIC programs, as well as *ad hoc* programs in Africa and South America. We noted that all programs are slightly different but generally share three key objectives: to justly compensate those who suffer adverse events following immunization (AEFIs); to maintain accountability and deflect lengthy and costly civil litigation cases; and to bolster public confidence in immunization programs.

According to the CDC, from 2006 to 2017 over 3.4 billion doses of covered vaccines were distributed in the U.S. In that same period, for every one million doses of vaccine that were distributed, approximately one individual was compensated. The introduction of new vaccines is typically associated with a spike in novel claims and injury compensation, but this levels-out fairly quickly. The predicted number of settlements and the cost of any program will depend on eligibility criteria, filing requirements, and the public's knowledge of the program.

[redacted]

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[redacted]

Furthermore, we understand that Canada will have appropriate surveillance systems in place to properly monitor and report AEFIs during COVID-19 immunization implementation. Surveillance is likely to be robust given that many of the same vaccines are being rolled out across many countries and so data can be collected globally. [redacted]

Overall, the CVTF recognizes and supports PHAC's analysis on the need for a vaccine injury compensation program that all Canadians, regardless of which province and territory they reside in, could have equitable access to. This is an international standard and not having a vaccine injury compensation program in place could seriously undermine our overall immunization programs.

[redacted]

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[redacted]

Health Canada Interim Order

We were pleased to welcome Dr. Celia Lourenco, of the Biologics and Radiopharmaceutical Drug Directorate (BRDD) at Health Canada to present an overview of the recently announced Interim Order (IO) for the expedited authorization of drugs related to COVID-19. Within the scope of the IO is a new drug or indication for an existing product that is regulated under the Food and Drugs Act (FDA) and directly treats, prevents, mitigates or manages key clinical manifestations caused by COVID-19.

[redacted] Such measures should help facilitate a supply of high quality, safe and effective vaccines for Canada.

Update on International Advance Purchase Agreements

The procurement team from PSPC and PHAC provided an update on the procurement of vaccine candidates. [redacted]

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[redacted]

Meeting with Ministers

Minister Hajdu, we were very appreciative that you took the time out of your busy schedule to come and speak to us at our meeting on the 24th [redacted]

[redacted]

[redacted]

Thank you again for your visit, Minister Hajdu, and we look forward to seeing you again on September 30th.

We also had the pleasure to welcome back Minister Anand to the CVTF for a discussion on procurement. [redacted] Indeed, Canada is gaining a reputation for being a credible, reasonable, capable partner who wants to get things done.

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Sincerely,

[redacted]

Joanne M. Langley
Co-Chair

[redacted]

J. Mark Lievonen
Co-Chair

cc.
Simon Kennedy
Stephen Lucas PhD
Iain Stewart
Mona Nemer PhD

Roger Scott-Douglas PhD

Annex A: Members of the COVID-19 Vaccine Task Force in attendance at the September 10th meeting

Annex B: Summary of Conflict of Interest Disclosures (September 10th, 2020)

Annex C: Members of the COVID-19 Vaccine Task Force in attendance at the September 17th meeting

Annex D: Summary of Conflict of Interest Disclosures (September 17th, 2020)

Annex E: Members of the COVID-19 Vaccine Task Force in attendance at the September 24th meeting

Annex F: Summary of Conflict of Interest Disclosures (September 24th, 2020)

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Annex A

Members of the COVID-19 Vaccine Task Force in attendance at the September 10th meeting

J. Mark Lievonen (co-chair), Past President of Sanofi Pasteur Limited

Joanne Langley (co-chair), Division Head of Infectious Diseases at the IWK Health Care Centre and Professor of Pediatrics and Community Health and Epidemiology at the Dalhousie University Faculty of Medicine

Alan Bernstein, President and Chief Executive Officer, Canadian Institute for Advanced Research (CIFAR)

Robert Brunham, Head of the Vaccine Research Laboratory at the British Columbia Centre for Disease Control and Professor of Medicine at the University of British Columbia

[redacted]

Chris Procyshyn, Chief Executive Officer and co-founder of Vanrx Pharmasystems

Benjamin Rovinski, Managing Director of Lumira Ventures

Lorne Tyrrell, Founding Director of the Li Ka Shing Institute of Virology and Distinguished University Professor at the University of Alberta

Sylvia van Drunen Littel-van den Hurk, Professor of Biochemistry, Microbiology & Immunology in the College of Medicine at the University of Saskatchewan and Program Manager of Viral Pathogenesis and Vaccine Development at the University of Saskatchewan's VIDO-InterVac

André Veillette, Professor in the Department of Medicine at Université de Montréal and Director of the Molecular Oncology Research Unit at the Montreal Clinical Research Institute (IRCM)

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Annex B

Summary of Conflict of Interest Disclosures (September 10th, 2020)

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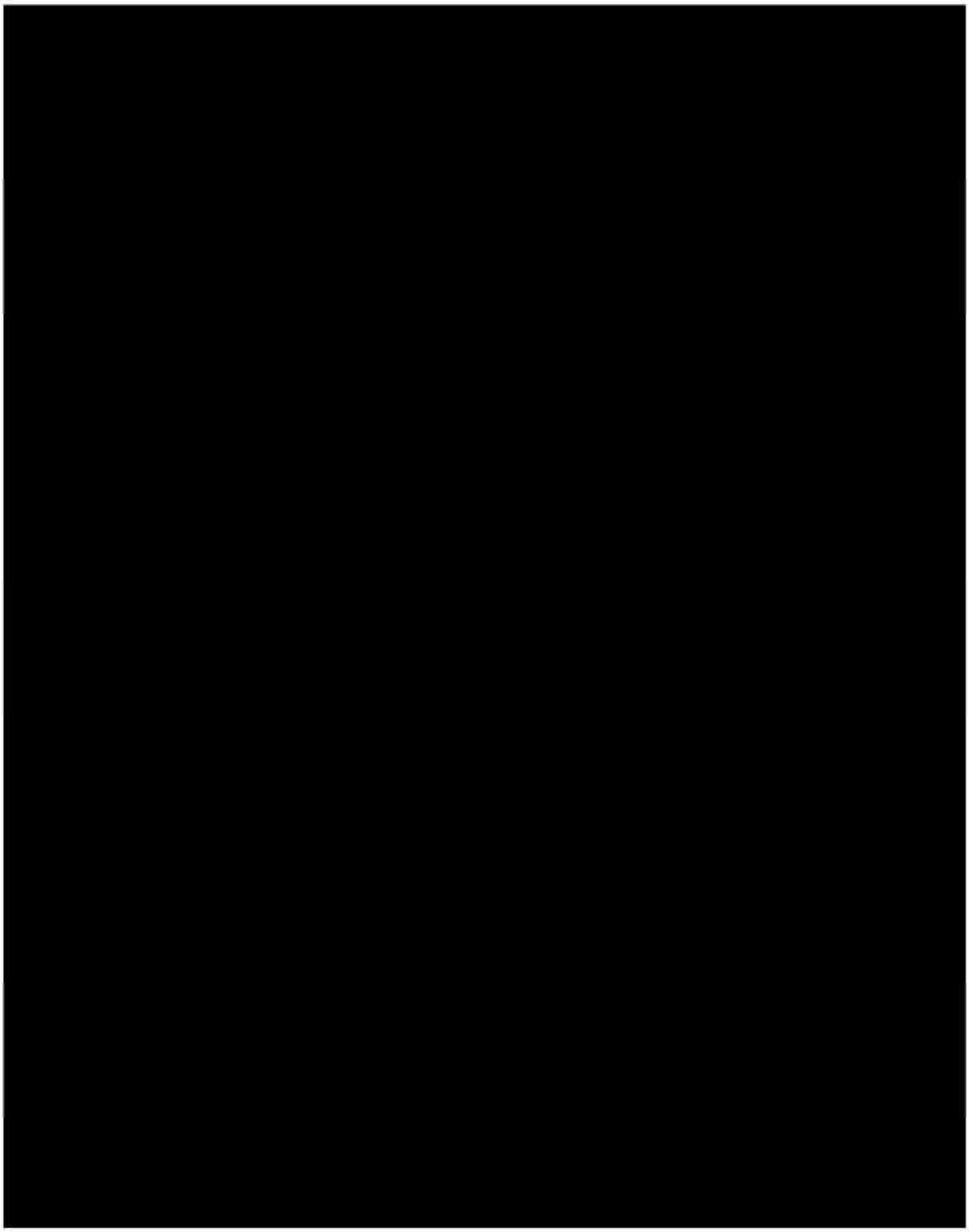

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Annex C

Members of the COVID-19 Vaccine Task Force in attendance at the September 17th meeting

J. Mark Lievonen (co-chair), Past President of Sanofi Pasteur Limited

Joanne Langley (co-chair), Division Head of Infectious Diseases at the IWK Health Care Centre and Professor of Pediatrics and Community Health and Epidemiology at the Dalhousie University Faculty of Medicine

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Annex D

Summary of Conflict of Interest Disclosures (September 17th, 2020)

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Annex E

Members of the COVID-19 Vaccine Task Force in attendance at the September 24th meeting

J. Mark Lievonen (co-chair), Past President of Sanofi Pasteur Limited

Joanne Langley (co-chair), Division Head of Infectious Diseases at the IWK Health Care Centre and Professor of Pediatrics and Community Health and Epidemiology at the Dalhousie University Faculty of Medicine

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Annex F

Summary of Conflict of Interest Disclosures (September 24th, 2020)

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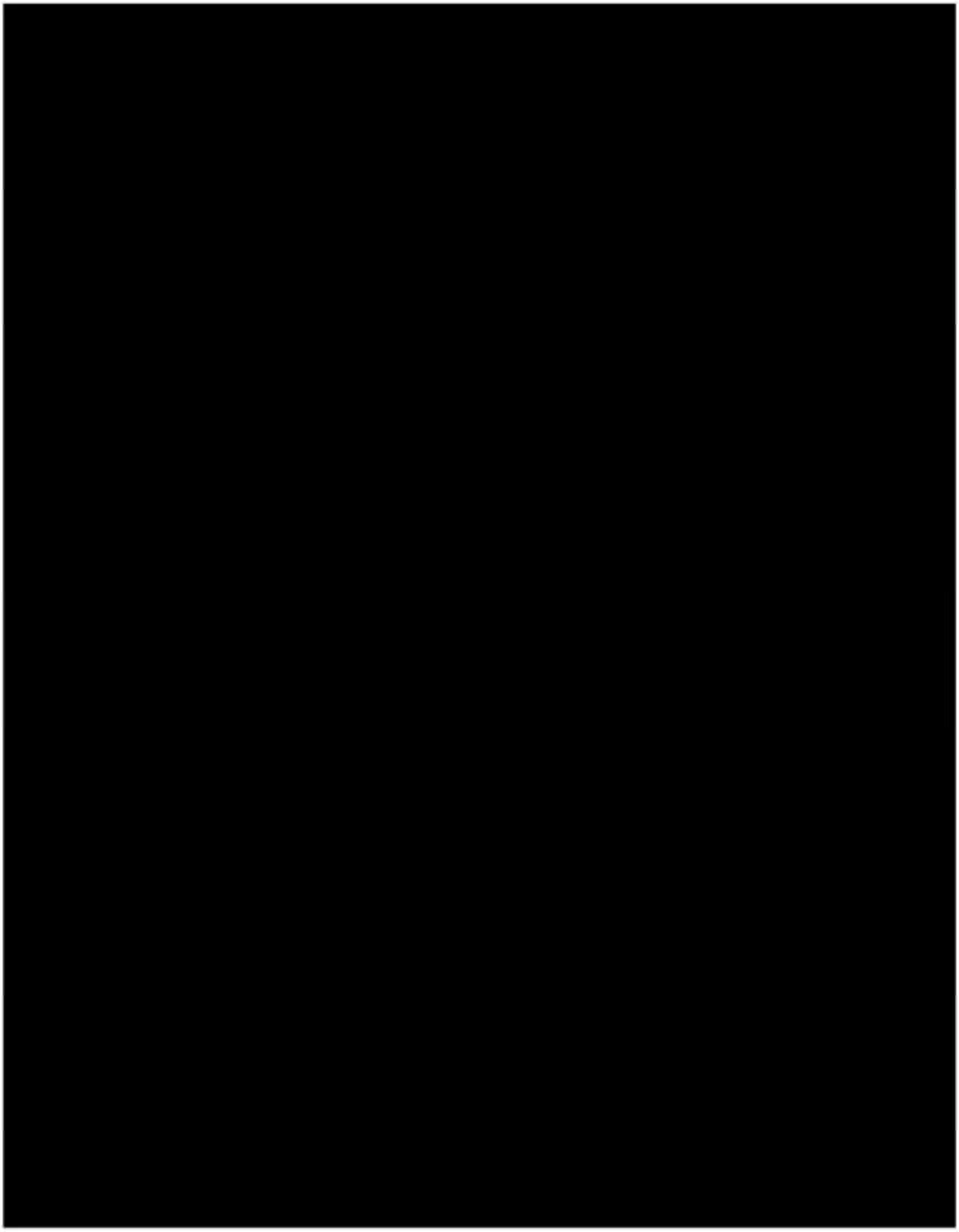

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Vaccine Injury Compensation Programs: Rationale and an overview of the Québec program

Eve Dubé[1,2]*, Dominique Gagnon[1], Noni E MacDonald[3], Shawn Harmon[3], Sandani Hapuhennedige[4]

Abstract

Vaccines are among the safest therapeutic agents, and serious adverse events rarely occur. When they do occur, an individual may have to bear some or all of the costs associated with their injuries, seek compensation through litigation or, if available, seek compensation from a publicly-supported Vaccine Injury Compensation Program (VIC Programs). The VIC Programs are "no-fault" compensation schemes in which governments compensate individuals who are harmed by properly manufactured vaccines. There are ethical, legal and practical rationales to support these programs. Worldwide there are 19 countries that have implemented VIC Programs; in the majority of these countries, vaccines are not mandatory. They all have similar processes with respect to process, standard of proof and elements of compensation. In Canada, only the province of Québec has a VIC Program, which has been running successfully since 1985. Concerns with VIC Programs include cost, difficulties assessing causality and concern that such programs may undermine public trust in vaccines; but these concerns can be addressed, especially in high-income countries that can bear the costs and have the capacity to manage the program.

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Suggested citation: Dubé E, Gagnon D, MacDonald NE, Harmon SHE, Hapuhennedige S. Vaccine Injury Compensation Programs: Rationale and an overview of the Québec program. Can Commun Dis Rep 2020;46(9):305–8. https://doi.org/10.14745/ccdr.v46i09a09

Keywords: vaccine injury, compensation, no-fault insurance, ethical considerations

Introduction

Vaccines are amongst the safest and most effective tools. Yet, vaccines—like any medical intervention—are not without a possibility of harm, albeit small. Most adverse events following immunization (AEFIs) are mild and resolve quickly and completely (e.g. fever, swelling at the injection site, rashes, etc.). In rare instances, however, serious adverse events can occur regardless of proper vaccine design, manufacture and delivery (1). A serious AEFI is defined as one that is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or results in a congenital anomaly/birth defect (2). The absolute risk of serious AEFIs is extremely low (e.g. fewer than one per 10 million doses for tetanus toxoid vaccines; 1–2 per one million doses for the inactivated influenza vaccine) (3). At a population level, these rare serious risks are far outweighed by the benefits of high uptake of vaccination. However, this implies that, in rare instances, an individual will suffer from significant consequences for the benefit of others, and that such an event can be anticipated (expected, even), though not necessarily predicted at the individual level (1).

The above state of affairs begs the question: What are the roles and responsibilities of jurisdictions for those who experience a "vaccine injury" (i.e. a serious AEFI) when given a vaccine recommended by public health? Halabi and Omer (3) identified three types of approaches toward AEFIs. While the acute costs of a serious AEFI are covered through the public healthcare system, for any additional costs, individuals may 1) bear the costs associated with their injuries by themselves, 2) seek compensation through litigation against private-sector actors (i.e. the vaccine manufacturers) or 3) seek compensation from publicly supported systems, or Vaccine Injury Compensation Programs (VIC Programs) (3).

The objective of this article is to provide a rationale and global overview of VIC Programs and to describe the situation in Canada and, specifically, in Québec. This is the seventh in a series of articles produced by the Canadian Vaccination Evidence Resource and Exchange Centre (CANVax). This Centre includes a group of multidisciplinary professionals that identify and create useful resources to foster vaccine uptake.

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Rationale for Vaccine Injury Compensation Programs

There are a number of reasons why jurisdictions have implemented VIC Programs. As noted by Looker and Kelly, these programs often arise from political and economic pressures, litigation threats and the imperative to ensure an ongoing vaccine supply (4,5). Generally, there are biological, ethical, legal and practical arguments supporting the implementation of VIC Programs (6).

- Biological: Vaccinations are extremely safe, but the possibility of harm in rare instances exists and has been recognized (e.g. anaphylaxis, intussusception from a rotavirus vaccine no longer used)
- Ethical: Vaccination benefits not only the vaccinated individual, but the whole community through herd immunity. Ethical principles of solidarity, reciprocity, fairness and justice all support the implementation of measures to compensate the few individuals who will be harmed by vaccines. These arguments are stronger in jurisdictions where governments use mandatory policies to ensure widespread vaccination
- Legal: We have developed a rights-based society where everyone's physical integrity is, in some measure, guaranteed, and where incursions against this integrity give rise to justifiable claims for redress
- Practical: Tort litigation relating to AEFIs is costly and uncertain, and exposure to this uncertainty and potential liability can discourage manufacturers from producing vaccines. The VIC Programs remove the uncertainty of litigation for manufacturers and ensure the security of vaccine supply. They also help to forge an environment in which vaccine innovation can occur

Global overview

A recent review has shown that compensation programs have been implemented in 19 jurisdictions worldwide. Interestingly, twelve of the jurisdictions with such programs have no vaccine mandates (**Table 1**) (4).

The VIC Programs are "no-fault" compensation schemes in which federal or provincial governments compensate individuals who are harmed by properly manufactured vaccines (3). There is considerable variability in how these programs are administered, who is eligible and which vaccines are covered, the decision-making process for administration and how funds are sourced and allocated (5). Looker and Kelly (1) have conducted an extensive review of common program elements (**Table 2**).

The Canadian situation

In Canada, with the exception of Québec, any major health care costs from vaccine injury are covered through the public healthcare system. If a disability occurs, support would likely

Table 1: Jurisdictions with Vaccine Injury Compensation Programs (including the year of introduction)

Vaccination is not mandatory	Vaccination is mandatory
Austria (1973)	France (1963)
Denmark (1972)	Hungary (2005)
Finland (1984)	Italy (1992)
Germany (1961)	Republic of Korea (1994)
Iceland (2001)	Slovenia (2004)
Japan (1970)	Taiwan (1988)
New Zealand (1974)	United States (1988)
Norway (1995)	
Québec (1985)	
Sweden (1978)	
Switzerland (1970)	
United Kingdom (1979)	

Sources: Looker and Kelly, 2011 (1); Attwell *et al.*, 2019 (4)

Table 2: Common elements in Vaccine Injury Compensation Programs

Element	Comment
Administration	Most compensation programs are enacted and run by the government at the national or sub-national levels
Funding	National, state or municipal treasuries Manufacturers' levy Vaccine tax
Eligibility	Only mandatory vaccines Only vaccines recommended by public health All licensed vaccines Only vaccines believed to have an associated risk (e.g. Vaccine Injury Table)
Process	The process is similar in most jurisdictions: • Threshold injury or disability criteria to be met before making a claim • Initial revision by an administrative body for initial eligibility and compensation decisions • Revision by external review committee if a claim is deemed complex or contentious • A formalized appeal process for claimants • Prioritization of timely resolution of claims
Standard of proof	"Balance of probabilities" (i.e. more evidence than not that a vaccine caused the injury) Probable cause "Preponderant probability"
Elements of compensation	Lump sum or reimbursement proportional to the severity of vaccine injury, including: • Unreimbursed medical costs • Disability pension • Non-economic loss, including pain and suffering • Death benefits • Compensation to family • Reasonable legal costs (in the United Kingdom, for both successful and unsuccessful claimants)

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Table 2: Common elements in Vaccine Injury Compensation Programs (*continued*)

Element	Comment
Litigation right	In most countries, claimants can seek either damage through the courts or compensation through the program, but not both Other countries adjust compensation payments if damage has been received through the courts

Source: Looker and Kelly, 2011 (1)

come from disability incomes for those who are covered. The only means for compensation beyond this is through litigation.

There is a limited understanding of the number and scope of vaccine-injury related lawsuits in Canada (5). We do know that very few cases reach the courts, and these are often in relation to procedural matters, not the merits of the cases (i.e. requests for certification as class actions, requests to have claims struck, etc.) (7). One exception is *Morgan vs. City of Toronto* (8), wherein the plaintiff sued the City of Toronto for damages stemming from chronic fatigue syndrome, which she alleged resulted from the city's negligent administration of hepatitis B vaccine in 1994. In dismissing the claim, the Court held that, while the standard for disclosure of risks is very high, not every suspicion of risk constitutes a "known" or "material" risk, and that the city did not breach the standard in failing to warn the plaintiff about possible effects that were not, at the time of the inoculation, considered material. Note that many more cases are adjudicated through bodies such as Workers' Compensation Tribunals and Workplace Safety and Insurance Appeals Tribunals, but no comprehensive survey of the outcomes of these cases have been conducted.

Québec's Vaccine Injury Compensation Program

The following description comes from the Québec Ministry of Health website (https://www.msss.gouv.qc.ca/en/). In 1979, a five-year-old girl, Nathalie Lapierre, developed viral encephalitis shortly after being vaccinated for measles, and was left severely disabled. Her parents brought an action against the Government of Québec for damages, including those relating to tutoring. In *Québec (Attorney-General) vs. Lapierre* (9), the Québec Court of Appeal held that, while there was a causal link between the vaccination and the injury, there was no fault on the part of the Province (or the administering nurse), and there was no obligation under Québec law to compensate in the absence of fault. In dismissing Lapierre's appeal, both the Court of Appeal and the Supreme Court of Canada observed that "an obligation independent of any fault in circumstances such as those of the case at bar would be an excellent thing, but it does not exist in our law at present". In the result, perhaps for political reasons, or in recognition of the demands of social justice, the Government of Québec provided some support to the family in this case. Subsequently, in 1985, it introduced its VIC Program, which was statutorily grounded in a new division of the *Public Health Protection Act*. A regulation specific to this program was adopted in November 1987, and the first claims for compensation were filed the following year.

The principle of the VIC Program is that the Québec's Minister of Health and Social Services must compensate anyone injured as a result of a voluntary vaccination with a vaccine or immunoglobulins against a disease or infection identified in the regulation, or any compulsory or imposed vaccination. The vaccination must have taken place in Québec, and the claim form must be filed within three years of the injury. The claim is reviewed by an external committee of experts in vaccinology who 1) makes recommendations to the Minister on the existence or lack thereof of a causal link between the injury sustained and the vaccination and 2) assesses, if required, the percentage of permanent impairment to the victim's physical or mental integrity, and other elements required regarding compensation.

The Minister then renders a decision. If the claim is rejected, the claimant is informed and has 60 days to file an appeal. If the claim is accepted, the amount of compensation is determined using earnings and medical costs. The Minister has entered into an agreement with the *Société de l'assurance automobile du Québec* whereby the *Société* calculates and pays the compensation in cases with a favourable decision. Amounts are calculated pursuant to the rules and regulations prescribed in the *Automobile Insurance Act* and are identical to those awarded in case of an automobile accident.

As of April 1, 2018, 228 completed claims have been submitted and 187 met the admissibility criteria and were evaluated. Of these 187 cases, 43 claims were accepted, which resulted in $5.49 million of compensation paid. There is usually between three and five claims per year, but 11, 16, nine and 28 claims were submitted between 2009 and 2012, respectively. In 2009–2010, 5.7 million Quebecers received the influenza A(H1N1) vaccine, and this increased vaccination rate could explain the increase in claims observed in the three years following the mass vaccination campaigns (10).

Concerns with Vaccine Injury Compensation Programs

Arguments against VIC Programs are often grounded on the costs of these programs, the difficulties with causality assessment (i.e. determining whether there is a causal relationship between a vaccine and a specific injury) and the concern that these programs can decrease public trust in vaccines and fuel anti-vaccination movements (4).

Some of these concerns regarding VIC Programs have been addressed. The experience in the 19 jurisdictions where such programs have been implemented indicates that costs are both manageable and predictable (7). One caveat, however, is that 17

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of these 19 countries are high-income countries, which means that, on the whole, they can bear the costs and have the capacity to manage the program.

Similarly, the difficulties with causality assessment appear to be resource dependent, as the countries who have adopted VIC Programs have had the expertise to assess vaccine quality and causality of injuries. Finally, to date, there is insufficient evidence to assess the concern regarding the potential to decrease public trust in vaccines. The absence of a VIC Program has not been identified as a major concern amongst those who are hesitant. There is no evidence to show that having VIC Programs support vaccine acceptance; however, when a VIC Program is adopted there could be a communication strategy that reassures the public that, much like accident insurance, if it does occur, they will be covered.

Conclusion

Many affluent countries have VIC Programs; Canada and the United States are the only G7 countries that do not. There is a strong public health justification for the implementation of VIC Programs. Although there is no direct proof that these programs improve vaccine acceptance, they do help to maintain vaccine supply. If and when other provinces and territories in Canada consider such programs, the ethical, legal, and practical considerations as well as the successful 35-year track record in Québec may help to inform this policy decision.

Authors' statement

ED — Writing original draft, review and editing
DG — Writing, review and editing
NEM — Writing, review and editing
SHEH — Writing, review and editing
SH — Writing, review and editing

Competing interests

E Dubé received grants from the Public Health Agency of Canada, the Québec Ministry of Health and Social Services, *les Fonds de recherche du Québec—Santé*, the Canadian Institutes of Health Research, the Canadian Immunization Research Network and the Social Sciences and Humanities Research Council of Canada. She is a member of the Canadian Vaccination Evidence Resource and Exchange Centre (CANVax) Team.

NE MacDonald received grants from the Public Health Agency of Canada, the World Health Organization, the Nova Scotia Health Research Foundation, the Canadian Institutes of Health Research, the Canadian Immunization Research Network and the Social Sciences and Humanities Research Council of Canada. She is a member of the CANVax Team.

Acknowledgements

Production of the Canadian Vaccination Evidence Resource and Exchange Centre (CANVax) briefs has been made possible through funding from the Public Health Agency of Canada. Thank you to the many authors, immunization partners, and reviewers who contribute to CANVax.

Funding

The development of the Canadian Vaccination Evidence Resource and Exchange Centre Briefs is supported by the Immunization Partnership Funds of the Public Health Agency of Canada.

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WITHHELD / RETENUE

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The head of a government institution may refuse to disclose, if the record came into existence less than twenty years prior to the request, any record requested under this Act that contains (a) advice or recommendations developed by or for a gove
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Canada

PAN-CANADIAN NO-FAULT VACCINE INJURY SUPPORT PROGRAM

Presentation to the CPHO's Health Professional Forum – March 24, 2021

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Outline

Purpose

- Provide an update on implementation of the pan-Canadian no-fault Vaccine Injury Support Program (VISP)

Overview of the presentation

- Recap and Drivers
- FTP engagement
- Program design details
- Third Party Administrator
- Next Steps

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Recap – VISP Drivers

The Prime Minister announced the creation of the VISP following the First Ministers' Meeting on December 10, 2020. The program will ensure that individuals who experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada, have fair and timely access to financial support.

Long-standing gap	• The VISP will strengthen Canada's immunization system. • Over 20 countries around the World have national vaccine injury support programs, including all other G7 countries.
Fairness and equity	• Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.
Leadership and responsibility	• Vaccines are a public good and in the rare event of serious and permanent injury, individuals should be supported, without having to go through litigation.

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Four main areas of work…

FPT Engagement

Program Design

Third Party Selection

Next Steps – Preparing for program launch

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FPT Engagement

- All P/Ts were invited to participate in the pan-Canadian VISP, or to develop their own programs with federal financial support.
- All jurisdictions will be participating in the federally-managed VISP, with the exception of the province of Quebec, who will maintain its existing program, which has been in place for over 30 years.
- Regular updates are provided to P/Ts via a number of established governance committees – CDMH, SAC, FPT VISP Committee

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Program Design

- No fault program, applying the balance of probabilities approach in determining causality.
- Injuries must be serious and permanent – e.g. VISP would not apply to anaphylactic reactions, unless they result in long term/permanent injury to patient.
- Applies to all vaccines and immunoglobulins administered prophylactically in Canada, not just COVID-19 vaccines.
- Intent is to align with Quebec's existing program as much as possible, to ensure equivalency across Canada.
- Financial support will include: injury indemnity; income replacement; death benefits; funeral expenses, and other expenses, such as uncovered medical expenses.
- Program will be delivered via a third-party.

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Third Party Selection

- The VISP will be administered through a Contribution Agreement, with a review after five years.
- The third party will be responsible for the entirety of the compensation process, including: claims intake; causality assessment; administration of financial payments; and appeals.
- An open Call for Proposals for a 3rd party to administer the program was launched on February 10, 2021, and closed on February 24, 2021.
- Proposals were evaluated by a multi-disciplinary Review Committee.
- PHAC anticipates to have a Contribution Agreement with the selected third party in place by early April 2021 with program launch in June 2021.

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Next Steps – Preparing for Program Launch

- Work with the third party with the objective to officially launch the program in June 2021 (TBC).

- Continue engagement and collaboration:
  - With P/Ts
  - With stakeholders and other partners

- Implement a comprehensive communications approach with partners and stakeholders to ensure awareness of VISP in the medical community and in the general population.
  - Communications to be in alignment with third party communications, who will become the detailed source of information for any questions that relate to eligibility and application process.

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UPDATE ON THE IMPLEMENTATION OF THE PAN-CANADIAN VACCINE INJURY SUPPORT PROGRAM

SUMMARY

- The Public Health Agency of Canada (PHAC) continues to make progress in implementing a pan-Canadian Vaccine Injury Support Program (VISP).
- [redacted]
- A Call for Proposals for a 3rd party to administer the program was launched on February 10, 2021, and closed on February 24, 2021. Proposals were received from four interested organizations.
- A Review Committee to evaluate these proposals was established with a diverse composition, including expertise in implementing compensation programs (inside and outside of government), medical expertise, and privacy management. Provinces and Territories were also invited to identify participants for the Review Committee, and a representative from New Brunswick participated.
- Following a review of all proposals, the Review Committee recommended Raymond Chabot Grant Thornton Consulting Incorporated (RCGT) as the best-suited 3rd party deliverer of the program.
- PHAC has undertaken additional due diligence, and concurs with this recommendation. Notifications to all applicants of the outcome of the process will be sent imminently, followed by the negotiation of an agreement with RCTG.
- PHAC anticipates finalizing a Contribution Agreement with RCGT by mid-April 2021, with the program officially launched by the 3rd party in June 2021.

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BACKGROUND:

- The VISP program was announced by the Prime Minister on December 10, 2020. Building on the model in place in Québec for over 30 years, VISP will ensure that individuals who experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada, have fair and timely access to financial support, without litigation.

- The implementation of a VISP addresses a longstanding gap in Canada's national immunization programming, and brings Canada in line with other G7 countries.

PROGRAM DESIGN:

- To be eligible to the program, the Health Canada authorized vaccine must have been administered in Canada on or after December 8, 2020.

- Claimants have three years from the date of their vaccination or death to file a claim.

- Financial support will include: injury indemnities; income replacement; death benefits; funeral expenses, and other expenses, such as uncovered medical expenses.

- The VISP will be administered through a Contribution Agreement with a third-party, with a review after five years.

- The third party will be responsible for the entirety of the compensation process, including: claims intake; causality assessment; administration of financial payments; and appeals.

THIRD PARTY SOLICITATION AND SELECTION:

- An Invitation to Submit a Funding Request (ISFR) was launched on February 10, 2021, and closed on February 24, 2021.

- Proposals were submitted by four interested organizations.

- A Review Committee to evaluate proposals was established with a diverse composition, including expertise in implementing compensation programs (inside and outside government), medical expertise, privacy management, and P/T representation.

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- The Review Committee undertook a full assessment on the quality, merit and relevance of proposals received, as well as how the funding request met the eligibility criteria and program objectives.

- The Review Committee has recommended Raymond Chabot Grant Thornton Consulting Incorporated (RCGT) as the best-suited 3rd party deliverer of the program.

- Based on a consensus recommendation by the Review Committee, as well as PHAC's internal assessment of the proposals, PHAC will proceed to enter into Contribution Agreement with RCGT.

PROVINCIAL AND TERRITORIAL ENGAGEMENT:

- All P/Ts have confirmed their participation in the federally-run pan-Canadian VISP, with the exception of Quebec, who will be maintaining its existing vaccine injury compensation program with support through federal funding. A separate Contribution Agreement will be negotiated with Quebec at a later date.

- PHAC continues to work closely with P/Ts. An F/P/T working group has been created and meets regularly. In addition, regular updates have been provided to the Special Advisory Committee on COVID-19, and the Council of Deputy Ministers of Health.

- PHAC continues to work closely with the Government of Quebec to ensure, to the extent possible, alignment between VISP and the Quebec program.

PROGRAM LAUNCH AND COMMUNICATIONS:

- PHAC is anticipating to have a Contribution Agreement with RCGT in place by early April 2021 with program launch in June 2021.

- It is recommended that the announcement of the selected 3rd party and program rollout be made in June 2021, once the 3rd party has sufficiently stood up the necessary operations to receive enquiries and claims intake.

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Meeting with Special Advisory Committee (SAC)
December 3, 2020

Speaking Points for Vice-President of the
Infectious Disease Prevention and Control Branch

CONTEXT

OBJECTIVE AND DISCUSSION FORMAT:
IDPCB VP will inform SAC members of the federal government's intent to implement a pan-Canadian no-fault Vaccine Injury Compensation program in the coming months.

A deck will be presented outlining the proposed program and forward plan, and a discussion will follow.

1. No-fault Vaccine Injury Compensation in Canada

Context: Recognizing that vaccination is an area of shared jurisdiction, a deck will be presented to inform provincial and territorial stakeholders of the federal intent to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program, while also acknowledging that both timing and communication of this program may impact public perceptions pertaining to an eventual COVID-19 vaccine. Next steps will be presented and discussed including but not limited to, support for clear and aligned messaging, opt-out options and federal funding for provincial programs that meet federally-established criteria.

The federal VIC program intends to draw lessons from Quebec's established and successful VIC program for its design and implementation.

Slide 2: Purpose and overview of presentation

- Today, I want to advise the table that the Government of Canada intends to implement a pan-Canadian no-fault Vaccine Injury Compensation (VIC) program to cover all Health Canada-approved vaccines administered as of

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January 1, 2021. There will be an opportunity for provinces or territories to opt out and administer a similar program, which I will talk about further in the presentation.

- I would also like to obtain your views and thoughts on how best to implement this program within the context of the COVID-19 vaccine roll out.

- Before we start our discussion, I would ask that we keep these discussions confidential for the time being. There are communications sensitivities in implementing a vaccine injury compensation program concurrent with the COVID-19 vaccine roll-out, which I will touch on a bit later in the presentation.

Slide 3: VIC program drivers

- Four key drivers are prompting this action now. There have been previous FPT discussions on VIC programming in the context of the National Immunization Strategy but it ultimately did not move forward.

- We now have an opportunity to close a long-standing gap, and implement a federal pan-Canadian program. We recognize that Quebec has provided leadership in this area, and we wish to see all Canadians enjoy the same benefits as those who are vaccinated in Quebec.

- We will be asking Canadians to roll up their sleeves for the Covid-19 vaccine and it's only fair that they have access to a no-fault compensation program for the rare instances where serious injury does occur.

ATIA - 21(1)(b) ATIA - 21(1)(a)

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- While the ethical principles are important, we also need to ensure that we are on a level playing field with other countries. [redacted]

Slide 4: Overview of VIC Program Elements

- This program would cover all vaccines approved by Health Canada. Compensation would be provided to individuals irrespective of fault, negligence, or parties involved.

- The assessment of injury causality is an essential element of the program and would be determined by an appropriate expert body.

- The only recourse currently available for Canadians outside of Quebec is to take manufacturers to court and seek damages – and to date, no court has awarded damages.

Slide 5: Overview of VIC Program Design

- The pan-Canadian program would be federally funded and administered by an arms-length Third Party. In the absence of a suitable Third Party, PHAC would be the administrator.

- We recognize that some jurisdictions may wish to administer their own program, or in the case of Quebec, continue administering their own program. [redacted]

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[redacted]

- Eligibility for the program would start on January 1, 2021. Canadians would have up to 3 years to file claims consistent with Quebec's requirements.

Slide 6: Key Considerations

- Canada is currently the only G7 country without a national vaccine injury compensation program and over 2 dozen countries now have some form of a program in place. We can expect the presence of a VIC to become increasingly important to vaccine manufacturers as more countries implement VIC programs.

- [redacted]

[redacted]

- Very little data is available on the effect on confidence in vaccines and immunization rates following the implementation of a no-fault VIC program in other countries. We are undertaking public opinion research to ensure that we understand the impacts that a program may have on the

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COVID-19 vaccine deployment, and are prepared to minimize any negative effects.

- Initial research results have indicated that learning about a pan-Canadian VIC program would either have no effect or a positive impact on intentions to be vaccinated against COVID-19 for a large majority of Canadians.

- We're aware that timing is a consideration on how a VIC program could be perceived by the public.

Slide 7: Communications Approach

- Given the considerations at play, we have started to develop a communications approach to manage potential communications risks.

- The planned approach would be low-key and integrated into the overall vaccine rollout communications planning.

- We have prepared some proposed key messages (in the annex), and will liaise with the FPT PHN communications table to assist with the coordination of complementary messaging.

Slide 8: Proposed Next Steps

- We will be bringing this topic forward to CDMH next week, and will engage with appropriate existing tables. We do not want to introduce an overly burdensome process when you are already very busy.

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- Provinces and territories will need to decide on their preferred course of action; that is, whether they wish to have their residents covered under the pan-Canadian VIC program being established or whether they would like to be supported with their own respective program, **by the end of December 2020**. Bilateral discussions would then ensue to discuss terms for opting out.
    - **Question for the table**: any thoughts on timelines and process for indicating interest in opt-out?

- As we move forward, we plan to engage with the CIC on program design and implementation, and can return to SAC to provide updates.
    - **Question:** What are views on future discussions and updates at SAC?

Additional questions for discussion

- Does anyone have preliminary thoughts they would like to share on vaccine injury compensation?
- Any experiences in other areas that you would want us to leverage?

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

[*Correspondent's Name, Title, & Address*]
xxxxxxxxxxxxx
xxxxxxxxxxxxxx
xxxxxxxxxxxxxx

Dear [*Name of Correspondent*]:

On December 10th, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3rd, 2020, and at the FPT Deputy Ministers of Health Committee on December 11th, 2020.

The VISP will be federally funded and provide coverage for all uninsured costs resulting from serious permanent injuries sustained following administration of any Health Canada-approved vaccines, including COVID-19 vaccines, as of December 8th, 2020. The expectation is that a third party administrator, selected through a competitive solicitation process, will manage the VISP; however, if a suitable third party cannot be identified, the Public Health Agency of Canada will administer the program. Our goal is to have a third party administrator in place and able to accept claims for compensation by June 1st, 2021. The initial agreement with a third party administrator will be for five years, with a review of the program at that time.

Recognizing that immunization is an area of shared responsibility while also ensuring that every Canadian has access to financial support, provinces and territories have the flexibility to opt out of the pan-Canadian VISP should they wish to develop and implement an equivalent program within their own jurisdiction. In such cases, federal funding would be available to support the

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provincial or territorial program, provided that it meets federal objectives and criteria.

A provincial or territorial program would need to encompass certain parameters, including:

- Program to be established in 2021 with coverage retroactive to December 8th, 2020;
- Coverage applying to all Health Canada approved vaccines;
- Program design to be "no-fault";
- Financial support to cover serious permanent injury;
- Applicants to have a three year window to apply for financial support; and
- Program to include an appeal mechanism for unsuccessful claimants.

In order to proceed with the next steps of implementing the pan-Canadian VISP, we are asking that you advise us whether your jurisdiction intends to be covered by the federal program or whether your jurisdiction wishes to implement its own specific program.

We kindly ask that you advise us of your intention by January 15th, 2021, to ensure sufficient time is available for bilateral engagements with jurisdictions, particularly with those who choose to opt out of the pan-Canadian VISP, to confirm program and funding parameters.

Please send your response and provide a point of contact for further discussions to Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca.

Sincerely,

Iain Stewart
President

cc: Stephen Lucas, Deputy Minister of Health Canada

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Canada

NO-FAULT VACCINE INJURY SUPPORT IN CANADA

FPT Conference of Deputy Ministers of Health – December 11, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- To discuss provincial and territorial interests in a federally-funded pan-Canadian no-fault Vaccine Injury Support program (VISP) covering all Health Canada authorized vaccines or immunoglobulins that protect Canadians from vaccine preventable diseases.

ATIA - 21(1)(a) ATIA - 21(1)(b)

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Considerations

Current lack of alignment with other G7 countries

[redacted]

Effect on vaccine confidence

- **Little data** available to assess if the introduction of no-fault VISP program is associated with an increase or decrease in immunization coverage rates, either immediately or over the longer term (see Annex 3).
- Transparency on vaccine communications overall supports vaccine confidence.

[redacted]

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Overview of VISP Elements

The program would provide support in the event of a serious vaccine injury (e.g. permanent disability or death):

- Serves five key functions, including: receiving claims; validating claims; assessing claims to determine causality; recommending/rejecting compensation; paying claims.
- Allows fair compensation for all Canadians who are injured or harmed, not just those from one province.
- Awards compensation irrespective of fault or negligence or parties involved.
- Includes coverage for all vaccines approved by Health Canada.
- Expected to apply to measurable uninsured damages or costs.
- Causality, degree of disability and compensation to be determined by an appropriate expert body.

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Overview of VISP Design

- Funded by the Government of Canada and administered by a Third Party. If no suitable Third Party is identified, program will be administered by Public Health Agency of Canada.

- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts. Decisions to award compensation would be made by the Third Party, in accordance with the funding agreement.

- Intention is to use Quebec's regime as the model for designing a pan-Canadian program to the extent possible, recognizing that it will not be feasible to duplicate every feature.

- Coverage will extend to all vaccines administered in Canadian territory **as of December 8, 2020**:
  - Ensures that compensation coverage will be in place prior to the administration of COVID-19 vaccine.
  - Formal program implementation, however, would follow by June 2021.

- P/Ts, including Quebec, will have the flexibility to opt out of the pan-Canadian program to administer an equivalent program, with federal funding provided if the program meets federal objectives.

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Communications Approach

- Begin to introduce vaccine injury support into communications with Canadians as part of updating them on COVID-19 vaccine roll-out plans.

- Approach VISP communications by integrating it into overall vaccine roll-out planning information to Canadians (part of entire suite of efforts) rather than shining a light on it as a new program.
  - Main message – an opportunity to strengthen Canada's immunization policy for all Canadians.

- Liaise with FPT PHN communications table to assist with coordination of complementary messaging.

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Proposed Next Steps

- Engagement with F/P/T Health Ministers (December 2020).
- Decision required by each P/T whether to opt-out of pan-Canadian VIC and establish equivalent program.
- Integrate VISP messaging and tactics into overall vaccine communications roll-out plan and develop evidence based messages designed to motivate the appropriate behaviour (underway).
- F/P/T engagement on program design and implementation (Winter 2021).
- Solicitation of interest and award of competitive process for a Third Party administrator (Spring 2021).
- Expected program launch, accepting claims for immunizations received as of December 8, 2020 (June 2021).

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Annexes

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Annex 1 – Sample Key Messages

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from an adverse reaction to a vaccine
  - This is extremely rare – less than one in a million

- In the rare event that a Canadian were to fall ill, they should not spend their time litigating in court for a settlement – they deserve fair compensation, which this program offers

- Establishing a vaccine injury support program is part of Canada's broader vaccine strategy and will help ensure we remain competitive in accessing new vaccines as they become available
  - We need Canada to be on an equal playing field with other countries
  - This VISP program brings Canada in line with its G7 counterparts that all provide VISP protection for a minimum of mandatory vaccines, with most covering all recommended vaccines

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Annex 2 – What we have learned from Quebec

- Quebec's successful no-fault VIC Program could provide the scope for a **pan-Canadian regime**.
- Since its creation by legislation, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec.

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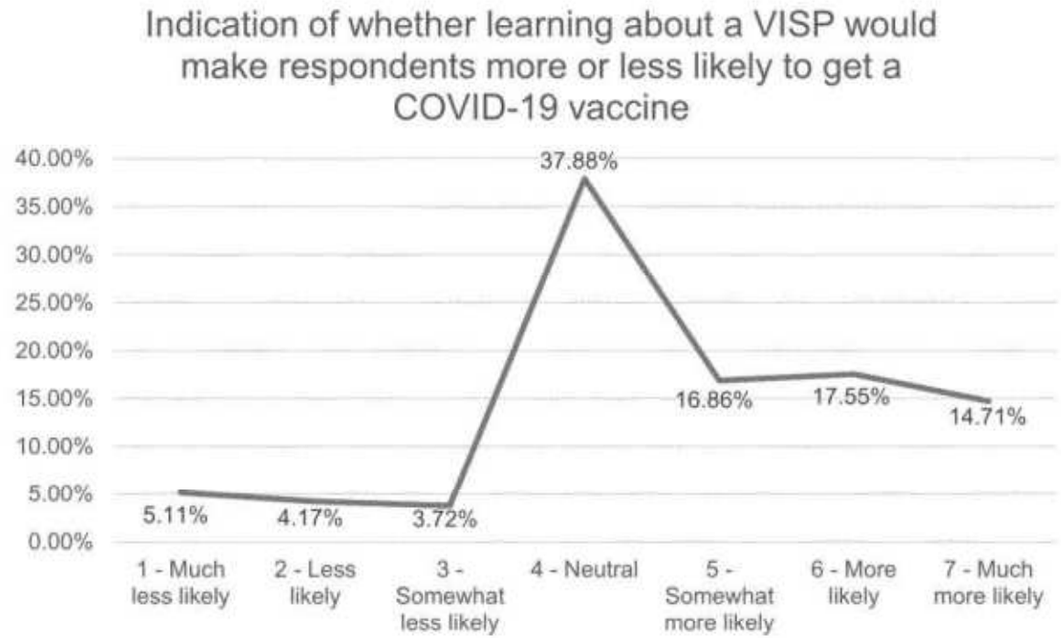
Annex 3 – Impact of VISP on Intention to Vaccinate

- Initial results from **research on the impact of learning about a national, no-fault VISP program on Canadians' intentions to be vaccinated against COVID-19*** conducted by PCO have revealed that:
  - Learning about a national VISP **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VISP would negatively impact their intentions to be vaccinated.



*Privy Council Office *Impact of a National, No-Fault Vaccine Injury Compensation Program on Intentions to be Vaccinated Against COVID-19: A Preliminary Analysis,* November 2, 2020. Sample size (n=1,580 Canadians).

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Meeting with FPT Canadian Deputy Ministers of Health
December 9, 2020

Speaking Points for Presenter (TBC)

CONTEXT

OBJECTIVE AND DISCUSSION FORMAT:
CDMH members will be informed of the federal government's intent to implement a pan-Canadian no-fault Vaccine Injury Support Program in the coming months.

A deck will be presented outlining the proposed program and forward plan, and a discussion will follow.

1. No-fault Vaccine Injury Compensation in Canada

Context: Recognizing that vaccination is an area of shared jurisdiction, a deck will be presented to inform provincial and territorial stakeholders of the federal intent to implement a pan-Canadian no-fault Vaccine Injury Support Program (VISP), while also acknowledging that both timing and communication of this program may impact public perceptions pertaining to an eventual COVID-19 vaccine. Next steps will be presented and discussed including but not limited to, support for clear and aligned messaging, opt-out options and federal funding for provincial programs that meet federally-established criteria.

The federal VISP program intends to draw lessons from Quebec's established and successful VISP program for its design and implementation.

Introduction (Iain Stewart):

- I'm pleased to introduce the next topic, a planned pan-Canadian no-fault Vaccine Injury Support Program. This is an exciting opportunity to close a long-recognized gap in Canada's immunization policy, and create a legacy for a

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stronger national immunization system that endures after the pandemic is over.

- I'll ask Kim Elmslie, Vice-President of COVID-19 Immunization Program at PHAC to provide an overview of the plan.

[Remainder of presentation to be delivered by Kim Elmslie]

Slide 2: Purpose and overview of presentation

- Today, I want to advise the table that the Government of Canada intends to implement a pan-Canadian no-fault Vaccine Injury Support Program (VISP) to cover all Health Canada-approved vaccines administered as of December 8th, 2020. There will be an opportunity for provinces or territories to opt out and administer a similar program, which I will talk about further in the presentation.

- I would also like to obtain your views and thoughts on how best to implement this program within the context of the COVID-19 vaccine roll out. The Special Advisory Committee discussed the proposed program last week and had a constructive conversation.

- Before we start our discussion, I would ask that we keep these discussions confidential for the time being. There are communications sensitivities in implementing a vaccine injury support program concurrent with the COVID-19 vaccine roll-out, which I will touch on a bit later in the presentation.

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Slide 3: VISP drivers

- Four key drivers are prompting this action now. There have been previous FPT discussions on injury compensation in the context of the National Immunization Strategy but it ultimately did not move forward.

- We now have an opportunity to close a long-standing gap, and implement a federal pan-Canadian program. We recognize that Quebec has provided leadership in this area, and we wish to see all Canadians enjoy the same benefits as those who are vaccinated in Quebec.

- We will be asking Canadians to roll up their sleeves for the Covid-19 vaccine and it's only fair that they have access to a no-fault compensation program for the rare instances where serious injury does occur.

- While the ethical principles are important, we also need to ensure that we are on a level playing field with other countries. [redacted]

Slide 4: Overview of VISP Elements

- This program would cover all vaccines approved by Health Canada. Compensation would be provided to individuals irrespective of fault, negligence, or parties involved.

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- The assessment of injury causality is an essential element of the program and would be determined by an appropriate expert body.

- The only recourse currently available for Canadians outside of Quebec is to take manufacturers to court and seek damages – and to date, no court has awarded damages.

Slide 5: Overview of VISP Design

- The pan-Canadian program would be federally funded and administered by an arms-length Third Party. In the absence of a suitable Third Party, PHAC would be the administrator.

- We recognize that some jurisdictions may wish to administer their own program, or in the case of Quebec, continue administering their own program. There is some flexibility to opt-out, but we will need to move quickly, and once the contribution agreement with the administrator is in place, the window to opt-out with federal funding will close for the duration of the agreement (5 years).

- Eligibility for the program would begin as of December 8th, 2020. Canadians would have up to 3 years to file claims consistent with Quebec's requirements.

Slide 6: Key Considerations

- Canada is currently the only G7 country without a national vaccine injury compensation program and over 2 dozen countries now have some form of a program in place. We

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can expect the presence of a VISP to become increasingly important to vaccine manufacturers as more countries implement VISP programs.

- [redacted]

- Very little data is available on the effect on confidence in vaccines and immunization rates following the implementation of a no-fault program in other countries. We are undertaking public opinion research to ensure that we understand the impacts that a program may have on the COVID-19 vaccine deployment, and are prepared to minimize any negative effects.

- Initial research results have indicated that learning about a pan-Canadian VISP program would either have no effect or a positive impact on intentions to be vaccinated against COVID-19 for a large majority of Canadians.

- We're aware that timing is a consideration on how a program could be perceived by the public.

Slide 7: Communications Approach

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- Given the considerations at play, we have started to develop a communications approach to manage potential communications risks.

- The planned approach would be low-key and integrated into the overall vaccine rollout communications planning.

- We have prepared some proposed key messages (in the annex), and will liaise with the FPT PHN communications table to assist with the coordination of complementary messaging.

- We would like to explore with you the possibility of announcing our joint intention to pursue the establishment of a VISP, possibly at the mid December Health Ministers' Meeting.

Slide 8: Proposed Next Steps

- Provinces and territories will need to decide on their preferred course of action; that is, whether they wish to have their residents covered under the pan-Canadian program being established or whether they would like to be supported with their own respective program, **by the end of December 2020**. Bilateral discussions would then ensue to discuss terms for opting out.

- We will be bringing this topic forward to a future HMM, and will engage with appropriate existing tables for implementation.

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- As we move forward, we plan to engage with the CIC on program design and implementation, continue to update SAC, and can return to CDMH to provide updates.

Additional questions for discussion

- Does anyone have preliminary thoughts they would like to share on vaccine injury compensation?
- Any experiences in other areas that you would want us to leverage?

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Canada

NO-FAULT VACCINE INJURY SUPPORT PROGRAM (VISP) IN CANADA

Health Ministers Meeting – December 17, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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Purpose

- To update Health Ministers on a federally-funded pan-Canadian no-fault Vaccine Injury Support Program (VISP) covering all Health Canada authorized vaccines or immunoglobulins that protect Canadians from vaccine preventable diseases.

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Overview

The establishment of a pan-Canadian no-fault vaccine injury support program (VISP) was announced by the Prime Minister on December 10th.

The objective of the program is to provide financial support to individuals in the rare instances where serious permanent injury occurs as a result of receiving an authorized vaccine (approved by Health Canada).

- Alternative to costly and lengthy litigation
- Recognizes that vaccination protects communities from infectious diseases and individuals who experience serious permanent vaccine injury should be compensated

VISP fills a gap in Canada's immunization system and provides equitable access to financial support.

- Quebec has offered a no-fault vaccine injury compensation program since 1985 and is the only jurisdiction that offers this type of program

VISP brings Canada into alignment with other G7 countries.

- [redacted]

Public health experts support introduction of the program.

- Lack of data on the impact of a no-fault VISP on immunization coverage rates (Annex 3)

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Vaccine Injury Support Program

- Funded by the Government of Canada and administered by a Third Party. If no suitable Third Party is identified, program will be administered by Public Health Agency of Canada.

- Administration would cover all aspects of the program, including claims intake, assessments, all decisions, and payouts. Decisions to award compensation would be made by the Third Party, in accordance with the funding agreement.

- Intention to use Quebec's regime as the model for designing a pan-Canadian program to the extent possible, recognizing that it will not be feasible to duplicate every feature.

- Coverage will extend to all vaccines administered in Canadian territory as of December 8, 2020:
  - Ensures that compensation coverage will be in place prior to the administration of COVID-19 vaccine.
  - Formal program implementation, however, would follow by June 2021.

- P/Ts will have the flexibility to opt out of the pan-Canadian program to administer an equivalent program, with federal funding provided the program meets federal objectives.

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Communications Approach

- A News Release was issued on December 10th as part of the First Minister's Meeting.
  - Main message – an opportunity to strengthen Canada's immunization policy for all Canadians.

- Highlight how VISP ensures that no Canadian is left behind in the rare event of a serious permanent injury due to vaccination and puts Canada on an equal playing field with other countries, helping with Canada's competitiveness in accessing vaccines.

- Liaise with FPT Public Health Network communications table to coordinate messaging.

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Next Steps

- Each P/T confirms participation in pan-Canadian VISP and or opt out with establishment of equivalent program (bilateral discussions initiated).
- Integrate VISP messaging into overall vaccine communications roll-out and reinforce program purpose (i.e. fill a gap in Canada's immunization system and align with other G7 countries) (underway).
- F/P/T engagement on program design and implementation (Winter 2021).
- Solicitation of interest and award via competitive process of funding to a Third Party VISP administrator (Spring 2021).
- Program launch, accepting claims associated with immunizations received as of December 8, 2020 (June 2021).

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Annexes

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Annex 1 – Sample Key Messages

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to experience a serious permanent injury due to vaccination
  - This is extremely rare – less than one in a million

- In the rare event that a Canadian were to experience a serious permanent injury, they should not spend their time litigating in court for a settlement – they deserve financial support, which this program offers

- Establishing a vaccine injury support program is part of Canada's broader vaccine strategy and will help ensure we remain competitive in accessing new vaccines as they become available
  - We need Canada to be on an equal playing field with other countries
  - This VISP brings Canada in line with its G7 counterparts that all provide VISP protection for a minimum of mandatory vaccines, with most covering all recommended vaccines

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Annex 2 – What we have learned from Quebec

- Quebec's successful no-fault vaccine injury compensation program could provide the scope for a **pan-Canadian regime**.
- Since its creation by legislation, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec.

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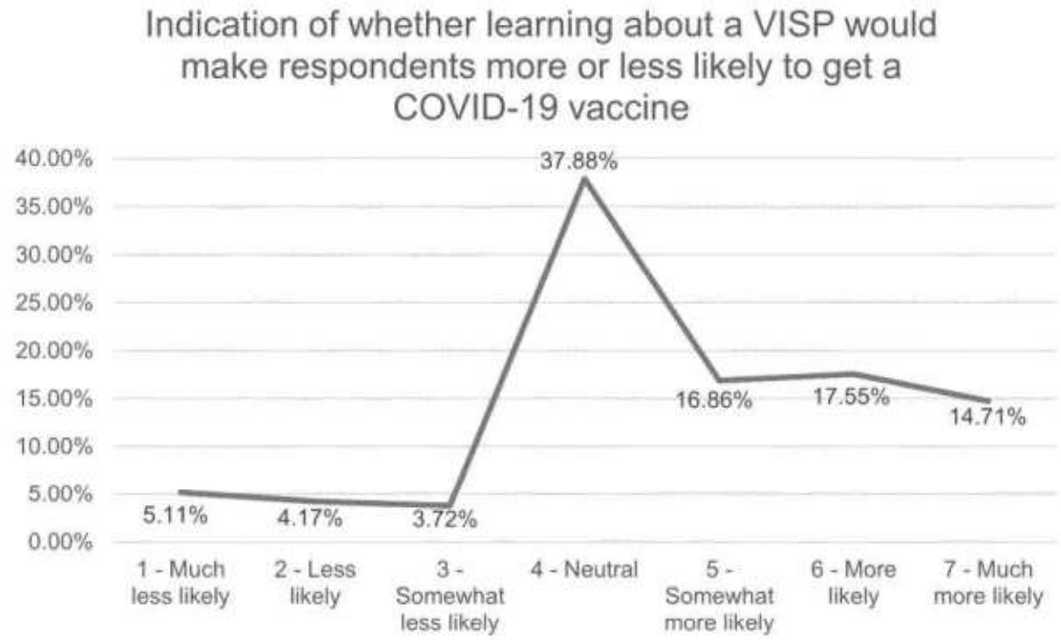
Annex 3 – Impact of VISP on Intention to Vaccinate

- Initial results from **research on the impact of learning about a national, no-fault VISP on Canadians' intentions to be vaccinated against COVID-19*** conducted by PCO have revealed that:
  - Learning about a national VISP **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VISP would negatively impact their intentions to be vaccinated.



*Privy Council Office *Impact of a National, No-Fault Vaccine Injury Support Program on Intentions to be Vaccinated Against COVID-19: A Preliminary Analysis,* November 2, 2020. Sample size (n=1,580 Canadians).

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From: Currie, Andrea (PHAC/ASPC)

Sent: 2020-07-03 2:20 AM

To: Tam, Dr Theresa (PHAC/ASPC)

Cc: Killen, Marita (PHAC/ASPC)

Subject: 3 items: Vaccine update, CCDR & new genomic study that reaches same conclusion as early phase CCDR article

Attachments: ccdrv46i78-eng.pdf; Bullets border issues July 2 CCDR article v3.docx; PHAC_ML_VaccinationSchedules_2020-04-23_1540_FINAL.docx

---

Hi Dr. Tam,

Gina Charros shared this update today that will appear in the Quick Facts tomorrow regarding **yesterday's press release on BioNTech and Pfizer's mRNA vaccine in development**.

- On July 1st, BioNTech (Germany) and Pfizer (U.S.) released positive preliminary clinical data on the safety and efficacy of their mRNA vaccine candidate being assessed in advanced Ph1/2 randomized controlled trials in Germany and the U.S.
- **This is the second vaccine in the world to have publishable results.**
- BioNTech and Pfizer have solid infrastructure for the manufacturing and distribution of MCMs.
    - They are gearing up to manufacture up to 100 million doses by the end of 2020, and potentially more than 1.2 billion doses by end of 2021 at sites in Germany and the U.S. pending regulatory approval.
- **We are assessing all international vaccine candidates as well as all available options with our international partners such as the WHO.**

https://investors.biontech.de/news-releases/news-release-details/pfizer-an
https://www.medrxiv.org/content/10.1101/2020.06.30.20142570v1.full.pdfd-biontech-announce-early-positive-data-ongoing-phase

Jul/August issue of CCDR was published today.
Substantive content in this edition includes:

- outbreak report by Montreal Public Health on a **mixed community and nosocomial outbreak of *Legionella pneumophila***
- overview of the **epidemiology of Cryptosporidiosis in Ontario following introduction of PCR testing** in 2018
- 6th in a series of articles about immunizations, this one summarising **considerations for mandatory childhood immunization programs**
    - emphasizes the need for a multi-pronged, tailored and nuanced approach noting that making vaccinations mandatory does not guarantee high coverage rates
    - section on "**COVID-19 vaccines and consideration for a mandatory approach**" consists of one paragraph (below)

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- *While a poll in Canada in late April 2020 reported strong support amongst the general public for making COVID-19 vaccination mandatory (21), this strategy can only be considered when these vaccines become widely available in Canada. Given that a mandatory program has costs both in terms of implementation and monitoring (5), decisions need to rest on what additional benefit is hoped to be achieved. If vaccine uptake is already expected to be high amongst groups deemed necessary for the control of the spread of COVID-19, then the added costs of a mandatory program are likely not justified. In contrast, if the rates of uptake are low and the ease of access and other strategies known to improve uptake have been addressed, then a mandatory approach may be worth pursuing. Careful attention must be paid to whether this will be an incentive or penalty program, how it will be monitored and by whom (5).*

- Attached - media lines re: vaccination schedules during COVID-19.

- COVID-19 and the **increasing need for sex-disaggregated mortality data in Canada and worldwide**, authored by the Centre for Biosecurity

  - Descriptive summary of findings from Italy and China; death data less subject to biases compared to case data

  - While distributions of cases vary by sex, men represent greater proportion of deaths in Italy and China

  - Important to collect sex data for deaths to inform equitable public health and clinical strategies

- A retrospective analysis of the **start of the COVID-19 epidemic in Canada** authored by Dana Paquette and PHAC surveillance and epidemiology colleagues. You previously reviewed this article. Chris Archibald provided the attached bullets (also copied below) for Howard.

  - General bullets related to CCDR article describing the early phase of Canada's COVID-19 epidemic:

    - CCDR article describes the epidemiology of the early phase of Canada's epidemic (cases with a symptom onset from January 1 to March 12, 2020, before governments at all levels implemented aggressive community-based public health measures to prevent onward spread)

    - 1,360 confirmed cases had a symptom onset on or before March 12.

    - However, at the time, due to inherent delays in reporting, only 153 laboratory-confirmed cases were reported in Canada by March 12.

    - There is a delay in case reporting systems that is to be expected. Once individuals begin to experience symptoms, there are delays regarding the time they see a physician, until their sample is tested, and the results of testing are reported to public health.

  - Specific bullets for travel-related cases:

    - During this time, more than half (57.8%) of the 1,360 cases were related to international travel: 52.2% (n=710) had a history of

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international travel and 5.6% (n=76) were linked to cases who had travelled.

- 703/710 cases who had traveled internationally provided specific information on countries visited. Of these:
- 34.7% of these cases reported travel to (or transit through) the United States,
- 18.6% had reported travel to either the United Kingdom or France.
- 1.4% of cases reported travel to China.
- Looking at cases retrospectively by date on onset, most imported cases to Canada in this period were from countries assessed by WHO as countries that had only imported cases or local transmission with most cases linked to other known cases, and so were not countries known to have significant community transmission.
- In retrospect, it is clear that what was reported at the time was only the tip of the iceberg and that the true extent of the global spread of the disease was not known at the time.

- ID News: Beware the public opinion survey's contribution to misinformation and disinformation in the COVID-19
  - One paragraph news item: *The COVID-19 pandemic has been accompanied by an "infodemic" of misinformation and disinformation (1). Given the large degree of uncertainty, the complexity of the science, and rapidly evolving knowledge, well-intentioned misinformation is not surprising. As scientists race to understand a new disease, partial information and guesswork fill the gap until reliable research evidence is established. Unfortunately, disinformation, defined as deliberately false or misleading information (2), can be expected when crises are used as opportunities to make money (3) or to undermine existing institutions, including education and health care systems. Regardless of intention, misleading information can spread rapidly in the era of social media and 24/7 news coverage, aided by the influence of fear, anxiety, and stress on learning, beliefs, and health decisions. It is therefore incumbent on those conducting COVID-19 rapid research, especially research associated with public awareness and knowledge translation, to avoid contributing to the spread of misinformation and disinformation through their work.*

Sjaarda C. **Chasing the origin of SARS-CoV-2 in Canada's COVID-19 cases: A genomics study.** Preprint (https://www.biorxiv.org/content/10.1101/2020.06.25.171744v1.full.pdf)
Marina flagged this article to her journal club on Canada Day
Chris A provided this short summary to Howard earlier today:

- Note this genomic study of COVID from cases in and around Kingston, Ontario, during March 18-30, 2020 (a period of time **slightly later than the period in our CCDR** article).
- Main conclusions:

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- The majority of infections originated from the USA, likely due to the vicinity of the border.
- The initial testing guidance focusing on symptomatic patients and those with a positive travel history to Asia may have contributed to undetected community transmission early in the course of the pandemic.

MARINA's Canada Day edition of Journal Club:
Since it is Canada Day, we picked **a study from Canada,** with all Canadian authors. It's a study looking at the **genetic fingerprint** of the first cases in and around Kingston, Ontario. One can look at the slight mutations and make a family tree, showing where the virus came from. This is labour intensive, and an expensive method, but I wanted to highlight it, as, if our cases remain low, this method may be used more and more by Public Health Laboratories for understanding chains of transmission and to determine the origins of importations.
If it's too much, and all you want is a nice day off, just click on the paper and look at the author names. The diversity of our country is so evident and a cause to celebrate who we are, what we have collectively created, and what we can accomplish together.
Happy Canada Day! Let's keep working hard to keep our country safe.
Marina

- The study authors report on the SARS-CoV-2 genome sequences that were collected from the initial (March 18-30, 2020) COVID-19 cases in eastern Ontario and the viral origins in Canada.
- Methods:
  - Samples from nasopharyngeal swabs were obtained from symptomatic patients at the Kingston Health Sciences Center and the surrounding hospitals.
  - Demographic data and travel history were extracted from a review of laboratory requisitions, hospital charts, and public health case investigation charts. Assessment of linked cases were derived from public health case investigation charts.
  - Underlying assumptions for the phylogenetic analysis included that 1) same variants were unlikely to have evolved independently, and 2) new mutations accrued at an average rate of 1 base pair every 7 to 21 days.
  - A reference sequence from Wuhan (Wuhan-Hu1/2019) was used as the root for the phylogenetic tree.
- Results:
  - An average of 1.3 million mapped reads were generated per sample. Most viral genomes contained between six to eight variants when compared to the reference genome.
  - Twenty-five collected genome sequences were classified into two large SARS-CoV-2 clades (the S-clade [n=2] and the G-clade [n=23]).

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Phylogenetic matching to the GISAID database resulted in the identification of 13 unique ancestral genomes. (Figure 1)

- As many **as sixteen unique infection events were estimated to have been represented in the obtained samples - at least three that were likely introduced from Europe and seven from the USA. None of the samples had Asian origin based on phylogeny**. (Table 2)
- **Four separate genomes were shared by multiple patients, suggesting a common origin or community spread during the early stages of the pandemic in Canada**.

- Considerations:
  - The relatively high mutation rate of SARS-CoV-2 can help distinguish primary and secondary infections in the span of one to two weeks.
  - The majority of infections originated from the USA, likely due to the vicinity of the border.
  - The initial testing guidance focusing on symptomatic patients and those with a positive travel history to Asia may have contributed to undetected community transmission early in the course of the pandemic.

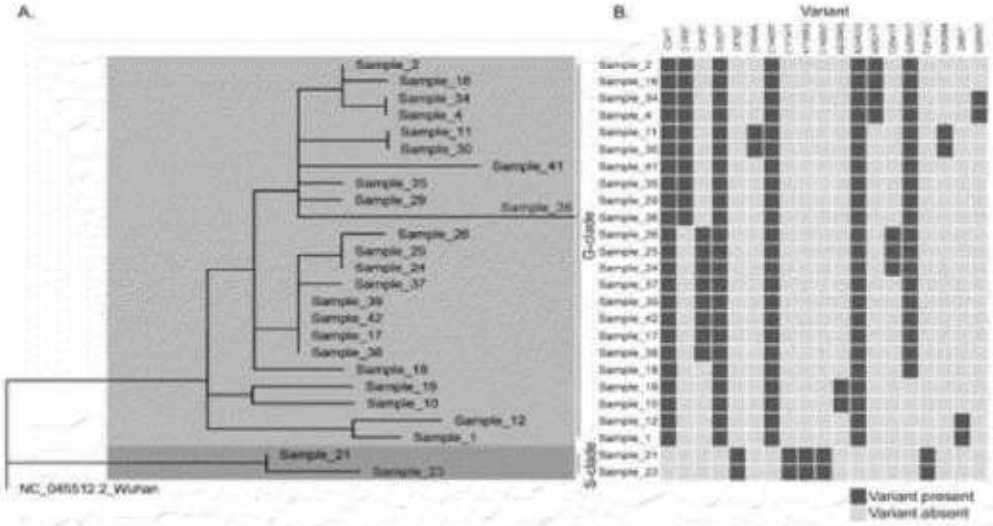

Figure 1. Clustering based on 25 SARS-CoV-2 genome sequences isolated from the early cases of COVID-19 in eastern Ontario. A. Maximum Likelihood Tree, rooted on the Wuhan reference strain, conducted by MEGA X using 45 variants discovered in 25 samples. B. Distribution of variants shared by two or more samples. Twenty-three viruses carry variants that characterize the G-clade of SARS-CoV-2 and two carry variants of the S-clade. *Variant at position 28881 is a GGG → AAC substitution.

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Table 2. Summary of viral origin of first COVID-19 cases into the eastern region of the province of Ontario, Canada. Phylogenetic analysis determined viral origin based on ancestral sequences in the GISAID database and correlated with patient's reported travel history. Samples with identical viral genome sequences are grouped into a single cluster and may represent shared origin or community transfer.

Sample ID	Clade	Cluster	Origin based on phylogeny	Reported Travel History or contact with known case
23	S-clade	1	North America – USA	
10	G-clade 1	2	Europe – UK/Spain	Travel: Europe – Ireland
1	G-clade 1	3	Europe – UK/Portugal	Travel: Europe – Portugal
12	G-clade 1	4	Europe – UK/Spain	Travel: Europe – Spain
18	G-clade 2	5	North America – USA	
17	G-clade 2	6	North America – USA	
38	G-clade 2	6	North America – USA	
39	G-clade 2	6	North America – USA	
42	G-clade 2	6	North America – USA	
24	G-clade 2	7	North America – USA	No travel: contact Samples 25, 26
25	G-clade 2	7	North America – USA	No travel: contact Samples 24, 26
26	G-clade 2	7	North America – USA	No travel: contact Samples 24, 25
37	G-clade 2	8	North America – USA	
2	G-clade 2	9	North America – USA	Travel: North America – Barbados
16	G-clade 2	10	North America – USA	No travel: contact Sample 4
4	G-clade 2	11	North America – USA	No travel: contact Sample 16
34	G-clade 2	11	North America – USA	Travel: USA – Florida
35	G-clade 2	12	North America – USA	
36	G-clade 2	13	North America – USA	
29	G-clade 2	14	North America – USA	
11	G-clade 2	15	North America – USA	No travel: contact out of province
30	G-clade 2	15	North America – USA	
41	G-clade 2	16	North America – USA	Travel: USA – Arizona

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Bullets for possible questions on border issues related to July 2 CCDR article on early phase of the COVID-19 epidemic in Canada

General bullets related to CCDR article describing the early phase of Canada's COVID-19 epidemic:

- CCDR article describes the epidemiology of the early phase of Canada's epidemic (cases with a symptom onset from January 1 to March 12, 2020, before governments at all levels implemented aggressive community-based public health measures to prevent onward spread)
- 1,360 confirmed cases had a symptom onset on or before March 12.
- **However, at the time, due to inherent delays in reporting, only 153 laboratory-confirmed cases were reported in Canada by March 12.**
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- 703/710 cases who had traveled internationally provided specific information on countries visited. Of these:
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    - 1.4% of cases reported travel to China.
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- **In retrospect, it is clear that what was reported at the time was only the tip of the iceberg and that the true extent of the global spread of the disease was not known at the time.**

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Media Lines

Vaccination Schedules during COVID-19

Issue:

In light of health considerations and strains on the healthcare system due to the COVID-19 pandemic, provinces and territories are updating guidance for continuity, prioritization and safe delivery of vaccination services. Some provinces and territories have adjusted their vaccination services to prioritize groups such as infants and young children, high-risk individuals, special populations and individuals requiring post-exposure prophylaxis. The National Advisory Committee on Immunization will be making recommendations on continuity of vaccination programs this spring.

National Immunization Awareness Week in late April is an opportunity to remind Canadians that vaccines are important, effective and safe for protecting our health, as well as the health of our families and communities.

The following high-level messages have been developed in anticipation of media questions.

Key messages:

- Vaccination is one of the most effective ways to prevent the spread of infectious diseases.

- Although public health is a shared responsibility in Canada, matters related to vaccination programs fall under provincial and territorial jurisdiction.

- Canadians should contact their health care provider or public health authority to see whether there have been any revisions to their or their family's recommended vaccination schedule as a result of the COVID-19 pandemic.

- Given the current pandemic, it is normal to feel concerned about visiting a doctor's office or clinic for routine appointments such as vaccinations.

- Canadians should consult with their health care provider or public health authority to:
    - find out whether there have been any revisions to their or their family's; recommended vaccination schedule as a result of the COVID-19 pandemic
    - determine when they should visit, and;
    - learn about the measures that have been put in place to safely deliver vaccination services during COVID-19.

- Health care providers have precautions in place to prevent the spread of infection during office visits. These precautions can include:

    - screening patients for symptoms or other risk factors before the appointment and upon arrival;
    - posting signage at the office;
    - encouraging patients to use alcohol-based hand sanitizer;
    - providing masks to patients upon arrival; and

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- staggering appointments to ensure physical distancing in the office.

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CCDR | CANADA COMMUNICABLE DISEASE REPORT

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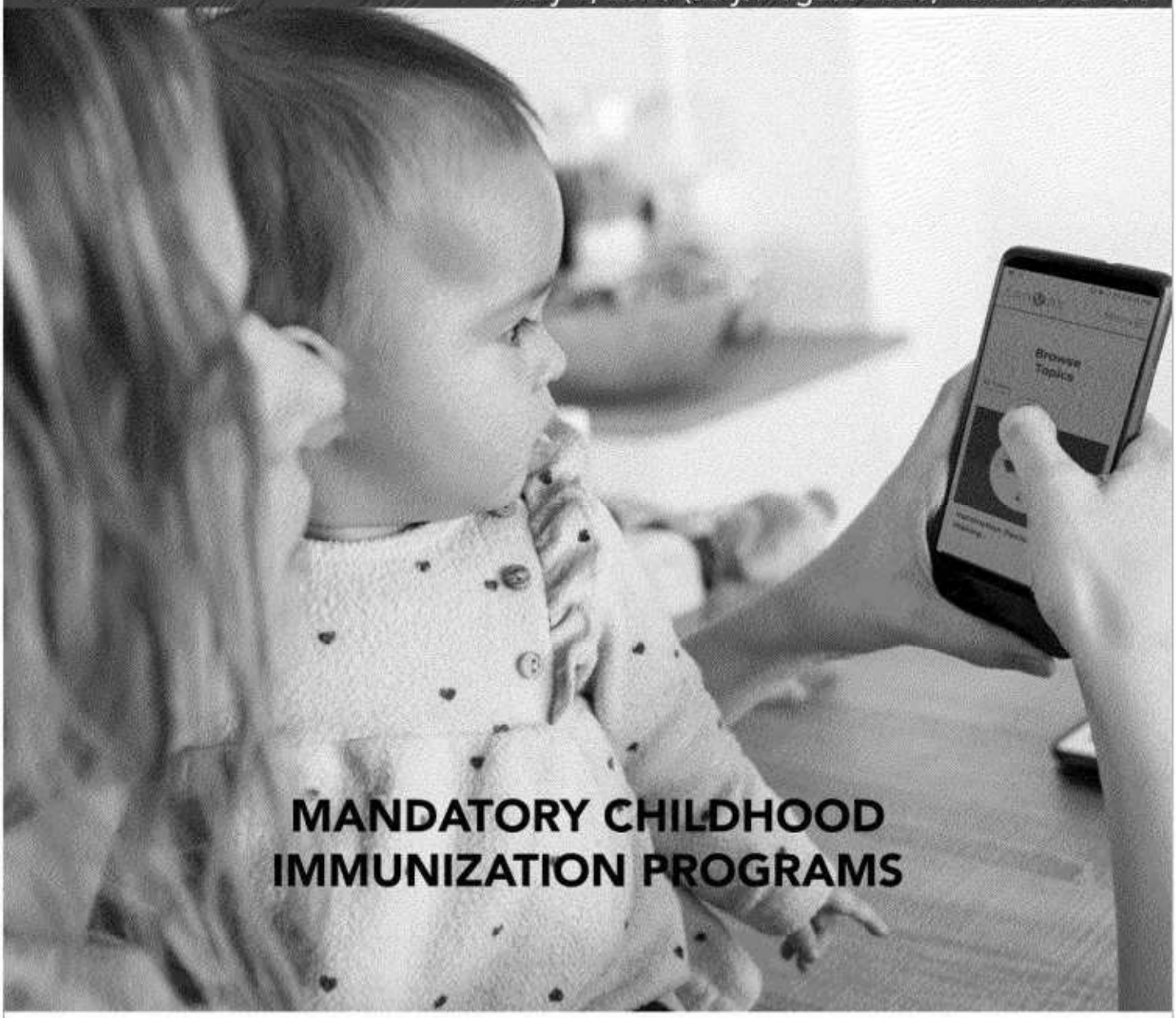
July 2, 2020 (July/August 2020) Volume 46–7/8



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CCDR
CANADA COMMUNICABLE DISEASE REPORT

The *Canada Communicable Disease Report* (CCDR) is a bilingual, peer-reviewed, open-access, online scientific journal published by the Public Health Agency of Canada (PHAC). It provides timely, authoritative and practical information on infectious diseases to clinicians, public health professionals, and policy-makers to inform policy, program development and practice.

The CCDR Editorial Board is composed of members based in Canada, United States of America, European Union and Australia. Board members are internationally renowned and active experts in the fields of infectious disease, public health and clinical research. They meet four times a year, and provide advice and guidance to the Editor-in-Chief.

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Photo Credit

The picture on the cover of this issue illustrates a young woman at home, consulting the CANVax website (Canadian Vaccination Evidence Resource and Exchange Centre) on her phone while her infant looks on. This was based on an Envato image that was adapted by Lyal Saikaly (https://elements.envato.com/young-woman-using-her-mobile-phone-while-her-baby--E8Y52LK).

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ISSN 1481-8531 / Cat. HP3-1E-PDF / Pub. 190563
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CCDR
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Mixed community and nosocomial outbreak of *Legionella pneumophila* in Montréal, Québec, 2019

Geneviève Cadieux[1]*, Julie Brodeur[1], Félix Lamothe[1], Cindy Lalancette[2], Pierre A Pilon[1], David Kaiser[1], Éric Litvak[1]

Abstract

Objectives: To describe the investigation of a community-based outbreak of *Legionella pneumophila* serogroup 1, with retirement home and acute care hospital sub-clusters in Montréal, QC, and the key challenges encountered.

Methods: There were 14 cases of *L. pneumophila* serogroup 1 infection with an onset date between June 7 and August 21, 2019. The environmental investigation included sampling of water cooling towers (WCTs) and other potential sources. Sequence-based typing of clinical and environmental isolates was performed. Public health interventions included WCT decontamination orders and communication with clinicians.

Results: Eleven (79%) of the 14 cases were immunosuppressed or immunocompromised. Most (13; 93%) were diagnosed using a urinary antigen test, and five (36%) had a culture. Two sub-clusters were identified: three cases in a retirement home and four cases on an acute care hospital floor. Typing results suggested that the same *L. pneumophila* serogroup 1 may have caused the community outbreak and the two sub-clusters. A matching environmental source was not identified.

Conclusion: Whereas typing of clinical isolates suggested a common environmental source, our investigation failed to identify this source. Future outbreak investigations could benefit from more clinical isolates for typing, local registries of water aerosolization sources other than WCTs, and ongoing access to all WCT routine monitoring results and *L. pneumophila* isolates for typing.

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Suggested citation: Cadieux G, Brodeur J, Lamothe F, Lalancette C, Pilon PA, Kaiser D, Litvak E. Mixed community and nosocomial outbreak of *Legionella pneumophila* in Montréal, Québec, 2019. Can Commun Dis Rep 2020;46(7/8):219–26. https://doi.org/10.14745/ccdr.v46i78a01

Keywords: *Legionella, Legionella pneumophila,* Legionellosis, Legionnaires' disease, disease outbreaks, communicable disease control, public health, water microbiology, water quality

Introduction

Legionella sp. infection became reportable in the province of Québec (QC) in 1987. Legionellosis incidence has been increasing since 2006 (1). In 2012, a *Legionella pneumophila* serogroup 1 outbreak in Québec linked to a water cooling tower (WCT) resulted in 183 cases and 13 deaths (1,2). Following this outbreak, the province introduced regulation that requires all WCTs to be registered with the Régie du bâtiment du Québec (RBQ) (3) and undergo routine maintenance and monthly monitoring for *L. pneumophila* (1). WCT sampling must be performed according to provincial guidelines (4), and results must be submitted monthly to the RBQ. The regulation requires WCT owners to take mitigation actions when results are between 10,000 and 999,999 colony-forming units (CFU)/L.

Furthermore, since July 2014, routine *L. pneumophila* monitoring results of 1,000,000 CFU/L or more must be reported to public health, and the reporting laboratory must keep the isolate for three months to facilitate public health investigation. The regulation also enables public health to issue decontamination orders to WCT owners (1,5). Preliminary data on a sample of over 300 WCTs suggest that the concentration of *L. pneumophila* in WCTs has decreased since the regulation was introduced in 2014 (6).

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However, although the number of legionellosis cases reported annually ranged from 11 to 19 between 2007 and 2014, the number increased thereafter, to 63 in 2018 and 55 in 2019. In 2018, three spatiotemporal clusters were identified, the largest involving nine cases. Despite extensive investigations, the source of these clusters was never identified. That year, 83 occurrences of *L. pneumophila* at levels of 1,000,000 CFU/L or more involving 70 WCTs were reported to the Montréal public health department (Direction régionale de santé publique de Montréal, or DRSP), of a total of approximately 1,300 registered WCTs in Montréal. Since routine monitoring of WCTs was implemented in 2014, neither a cluster nor a sporadic case of legionellosis has been successfully matched to a WCT in Montréal.

The objective of this report is to describe the investigation of a mixed community and nosocomial outbreak of legionellosis, in spring/summer 2019, in Montréal. Some of the 14 people infected included patients on an acute care hospital ward for immunocompromised and immunosuppressed patients with very limited outdoor exposure. The report highlights the continuing challenges public health faces in identifying and controlling sources of *Legionella* outbreaks in large, densely populated urban areas where there are multiple possible sources of *Legionella*, in spite of a provincial WCT registry and legally mandated monthly routine monitoring for *L. pneumophila*.

Methods

Spatiotemporal cluster detection

A spatiotemporal cluster of three community-acquired cases of legionellosis reported within a period of 27 days was first detected on July 10, 2019, through SaTScan routine daily automated spatiotemporal cluster analysis of local reportable disease data. Manual review of this cluster identified a fourth case reported within a 28-day window; all four cases were infected with *L. pneumophila* serogroup 1.

Case investigation

The provincial legionellosis case definition requires the presence of a compatible clinical presentation and laboratory confirmation of infection from an appropriate clinical specimen (typically a urinary antigen test or sputum culture) (3). All cases reported to the DRSP are investigated using a standard provincial questionnaire (3); data are collected on risk factors (including diabetes, chronic lung disease, cardiovascular disease, chronic renal disease, disease or drug-related compromised immunity, cancer, chemotherapy or radiation in the last six months, smoking, alcohol use); clinical presentation; diagnostic test results; complications; and potential exposures during the incubation period (including travel, health care, spa/pool, decorative fountains, drinking water fountains, grocery stores, greenhouses, water parks, drinking water supply issues, issues with plumbing, equipment that produce aerosols, water heater temperature, dental treatments, occupational and potential workplace exposures). For cases associated with a spatiotemporal cluster or outbreak, detailed information is collected on all sites visited during the incubation period (3). Public health investigators routinely ask treating physicians to consider also ordering a sputum culture for *Legionella* for cases with a positive urinary antigen test.

A confirmed outbreak case was defined as one that met the provincial legionellosis case definition (3); had a culture positive for *L. pneumophila* serogroup 1 with a sequence type consistent with the other outbreak cases; and had resided or worked within 3 km of the cluster's epicentre during their incubation period. A probable outbreak case met the provincial case definition for legionellosis (3); had only a positive urinary *L. pneumophila* serogroup 1 antigen test; and had resided or worked within 3 km of the cluster's epicentre during their incubation period. The usual incubation period of 2–10 days was extended up to 21 days for immunocompromised and immunosuppressed patients; the incubation period for the first four cases that launched the cluster investigation was May 24 to June 28, 2019.

During the case investigation, two sub-clusters were identified: three cases in a retirement home and four nosocomial cases in an acute care hospital. The residents of the retirement home lived on different floors and in different towers. The nosocomial cases had been hospitalized on the same floor for the entire incubation period (more than 21 days).

Environmental investigation

The WCT with *L. pneumophila* serogroup 1 levels of 1,000,000 CFU/L or higher nearest to the epicenter during the incubation period was about 8 km away, so it was more likely that a closer WCT with a lower *L. pneumophila* concentration could be DRSP requested monthly *L. pneumophila* testing results from May through July for all 59 WCTs (38 sites) within this zone from RBQ (3). Manual review of these results identified two WCTs with *L. pneumophila* serogroup 1 concentration below 1,000,000 CFU/L, 16 with missing results and none showing "interfering flora" (which could hide *L. pneumophila*).

After a fifth case of *L. pneumophila* serogroup 1 within the same geographic area was reported on July 12, DRSP issued a public health order to the RBQ to obtain water samples for retesting of the 18 WCTs with abnormal or missing results. The RBQ follows the provincial guideline for WCT sampling (4); the sampling procedure is the same for routine monthly monitoring as for outbreaks: a single 1 L water sample is obtained from a representative site after letting the water run for at least 30 seconds to purge stagnant water.

As more cluster cases were reported, the epicentre and the 4 km radius zone around it were adjusted slightly. DRSP requested the RBQ updated results of routine *L. pneumophila* monitoring for all WCTs located within the zone from on July 19 and 31 and August 12. On August 26, because a source had not yet been identified, DRSP requested that all available isolates from

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WCTs located within 12 km of the epicentre and with monthly *Legionella* monitoring results of 1,000,000 CFU/L or more at any time during the cases' incubation period be sent to the laboratory for sequence-based typing.

Concurrently, based on provincial guidance (3) and the scientific literature (7–11), DRSP accessed available databases of built water features and construction sites impeding road circulation as well as satellite images to identify other potential sources of *L. pneumophila* serogroup 1 aerosolization within a 2 km radius of the epicentre. During a field visit on August 7, water and/or biofilm specimens were collected from a high-pressure paint-stripping device and a water hose used for compacting the ground at a nearby excavation site. Water samples from a golf course irrigation system (i.e. sprinklers in three separate areas closest to the cases) were obtained on August 15.

Separate environmental investigations were also performed for the two sub-clusters of cases at the retirement home and acute care hospital. DRSP reviewed the heated pool and spa maintenance logs and hot water reservoir temperatures at the retirement home. Water samples from the hot water reservoir, heated pool, spa and outdoor decorative fountain and drinking water from the separate apartments of two residents who had become infected were collected on July 25.

The acute care hospital infection prevention and control team investigated potential sources on the affected floor. Water/biofilm samples were collected from sinks, taps and showerheads on July 24 and August 13 and from an ice machine, refrigerator, floor-cleaning machine and outdoor garden hose on August 13.

Laboratory analyses of clinical and environmental specimens

The diagnosing hospital performed the initial analysis of clinical specimens; these specimens or isolates were then forwarded to the provincial public health laboratory for confirmation and typing. On clinical specimens, routine confirmation methods included a locally-developed real-time polymerase chain reaction (PCR) targeting *ssrA*, *mip* and *wzm* genes; on clinical isolates, confirmation was performed using matrix-assisted laser desorption/ionization-time of flight (MALDI-ToF, Bruker, IVD 3,2) and serogroup 1 was identified by agglutination test slide with *L. pneumophila* serogroup 1 antisera (Denka Seiket, Japan). Genotyping was performed by sequence-based typing according to the European Working Group for Legionella Infection (EWGLI) protocol (12,13).

The *Centre d'expertise en analyses environnementales du Québec* (CEAEQ) conducted the culture and quantitative real-time PCR (*L. pneumophila* serogroup 1) analyses of WCT water samples obtained following the public health order. Analyses of environmental samples other than WCTs were performed by different commercial laboratories accredited by the CSA Group (*L. pneumophila* qPCR) and the CEAEQ (*Legionella* culture). All *L. pneumophila* serogroup 1 environmental isolates were forwarded to the provincial public health laboratory for typing.

Interventions

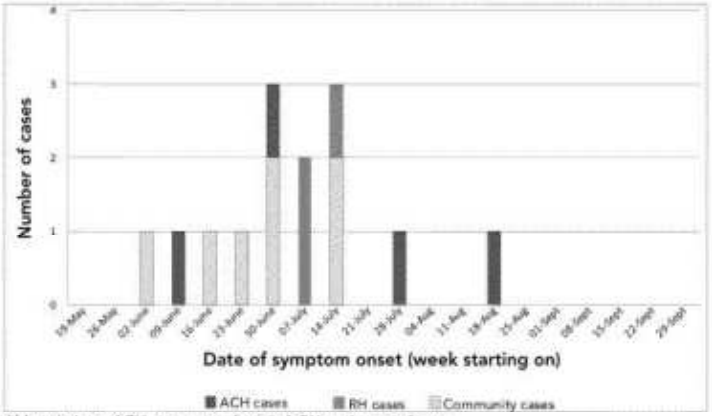
As a precaution, a decontamination order, effective immediately, was issued to all owners/managers of the WCTs that tested positive for *L. pneumophila* (any quantifiable result). The environmental health team from the DRSP followed up with each WCT owner/manager to make sure that decontamination was completed as soon as possible. Decontamination effectiveness was verified through repeat WCT sampling 2 to 7 days later, as per the provincial protocol (4). A public health alert was sent to Montréal clinicians to remind them to test for legionellosis in at-risk patients presenting with pneumonia and to order a sputum culture for *Legionella* to facilitate public health investigation. The outbreak was declared over on October 18, 45 days after the last case was reported to public health.

Results

Epidemiologic investigation

The outbreak comprised 14 cases of *L. pneumophila* serogroup 1, with illness onset between June 7 and August 21, 2019 (**Figure 1** and **Table 1**). Among the 14 cases, ten were male, median age was 68 years, 11 were immunosuppressed or immunocompromised, four required admission to an intensive care unit, two were intubated and one died. Six cases lived in private homes and three in the same retirement home (in different towers and on different floors); four were hospitalized on the same hospital floor for the duration of their incubation period and one lived in an independent living facility for persons undergoing cancer treatment near the acute care hospital.

Figure 1: Epidemic curve for the legionellosis outbreak in Montréal, 2019



Abbreviations: ACH, acute care hospital; RH, retirement home

Thirteen cases were initially diagnosed through a positive urinary antigen test; positive sputum cultures were subsequently obtained for four of them (Table 1). One anuric patient was initially diagnosed through a sputum culture.

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Table 1: Outbreak-related *Legionella pneumophila* serogroup 1 cases in Montréal, 2019

Case ID	Date reported	Date of illness onset	Sex	Age group (years)	Risk factors	Urinary antigen test	Sputum/ BAL culture	Complications	Exposure setting
1	2019-06-13	2019-06-07	F	85–89	Chronic lung disease; immunosuppression; cancer; cigarette smoking	Positive	ND	Hospitalized	Private home
2	2019-07-03	2019-06-26	M	25–29	Immunosuppression; cancer	Positive	ND	Hospitalized	Private home
3	2019-07-05	2019-06-30	M	65–69	Diabetes; chronic renal disease; cigarette smoking; alcohol consumption above lower-risk drinking guidelines	Positive	Positive	Hospitalized; ICU stay; intubated	Private home
4	2019-07-09	2019-06-18	M	65–69	Diabetes; immunosuppression; chronic renal disease; cigarette smoking	Positive	ND	Hospitalized; ICU stay	Private home
5	2019-07-12	2019-07-10	F	75–79	Diabetes; cardiovascular disease; chronic renal disease; immunosuppression; cancer; alcohol consumption above lower-risk drinking guidelines	Positive	ND	Hospitalized	Retirement home
6	2019-07-15	2019-07-02	F	30–34	Immunosuppression; cigarette smoking	Positive	ND	Hospitalized	Private home
7	2019-07-19	2019-07-14	F	80–84	Cardiovascular disease; chronic renal disease	Positive	ND	Hospitalized	Private home
8	2019-07-19	2019-07-10	M	75–79	Diabetes; cardiovascular disease; cigarette smoking	Positive	ND	Hospitalized	Retirement home
9*	2019-07-22	2019-07-01	M	55–59	Immunosuppression; cigarette smoking	Positive	Positive	Hospitalized	Acute care hospital
10	2019-07-22	2019-07-15	M	60–64	Diabetes; cardiovascular disease; chronic renal disease; immunosuppression	ND (anuric)	Positive	Hospitalized; ICU stay; intubated	Acute care hospital
11	2019-07-22	2019-07-20	M	60–64	Immunosuppression; cancer	Positive	Positive	Hospitalized; ICU stay; death	Cancer care home
12	2019-07-24	2019-07-16	M	70–74	Diabetes; cardiovascular disease; immunosuppression; cigarette smoking	Positive	Positive	Hospitalized	Retirement home
13	2019-08-12	2019-08-03	M	75–79	Diabetes; chronic lung disease; cardiovascular disease; immunosuppression; cigarette smoking	Positive	ND	Hospitalized	Acute care hospital
14	2019-09-03	2019-08-21	M	50–54	Immunosuppression	Positive	ND	Hospitalized	Acute care hospital

Abbreviations: BAL, bronchoalveolar lavage; F, female; ICU, intensive care unit; M, male; ND, not done
* Not a resident of Montréal

At 63.8 years (standard deviation: 17.6; median: 68 years), outbreak cases tended to be younger than other 2019 Montréal cases of *L. pneumophila* serogroup 1 infection whose mean age was 69.1 years (standard deviation: 11.7; median: 65 years). A larger proportion had comorbidities including compromised immunity or immunosuppression (see **Table 2**). A detailed review of findings from case investigations did not identify any common exposures between cases other than place of residence.

Environmental investigation

A total of 18 WCTs with abnormal or missing monthly monitoring results were initially sampled by order of the DRSP on July 13–18. Samples were first analyzed for *L. pneumophila* by qPCR, and if positive, by culture (**Table 3**). A positive quantifiable culture result was only obtained for one WCT (WCT-A). Review of updated monthly monitoring results on August 12 identified three WCTs with abnormal culture results in July; the isolates from two WCTs were still available (WCT-B and WCT-C), but the third had already been discarded. A resampling order was issued,

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Table 2: Characteristics of *Legionella pneumophila* serogroup 1 cases in Montréal in 2019

Characteristics	Cases linked to this outbreak (N=14)		Other cases in Montréal in 2019 (N=41)	
	n	%	n	%
Age group (years)				
25–34	2	14	0	0
35–44	0	0	0	0
45–54	1	7	3	7
55–64	3	21	16	39
65–74	3	21	10	24
75–84	4	29	5	12
Older than or 85	1	7	7	17
Comorbidities (self-reported)				
Diabetes	7	50	12	29
Chronic lung disease	3	21	6	15
Cardiovascular disease	6	43	21	51
Chronic renal disease	5	36	5	12
Immunosuppression	11	79	6	15
Other risk factors (self-reported)				
Smoking	8	57	27	66
Alcohol consumption above low-risk drinking guidelines[a]	2	14	8	20
Diagnostic test				
Positive urinary antigen test	13	93	40	98
Positive sputum or BAL culture	5	36	5	12
Severity				
Hospitalization	14	100	41	100
ICU admission	4	29	11	27
Intubation	2	14	6	15
Death	1	7	1	2

Abbreviations: BAL, bronchoalveolar lavage; ICU, intensive care unit
[a] Women: >10 drinks/week; men: >15 drinks/week (14)

but the sample tested negative. Twelve other WCTs located 4 to 12 km from the epicentre had routine *L. pneumophila* monitoring results of 1,000,000 CFU/L or more during the combined incubation period of our cases. The provincial public health laboratory conducted typing of all 15 quantifiable *L. pneumophila* serogroup 1 culture isolates.

Samples from all other potential outdoor community sources tested negative for *L. pneumophila* by qPCR. Samples from the retirement home (hot water reservoir, heated pool, spa, outdoor decorative fountain and drinking water) were all negative for *L. pneumophila* by qPCR. All hospital samples taken on July 24

Table 3: Results from culture and sequence-based typing of WCT isolates

WCT	Distance to epicentre (km)	*Legionella* culture result (CFU/L)[a]	Sequence-based typing results						
			flaA	flaA	flaA	flaA	flaA	flaA	flaA
A	1.2	10,000	1	4	3	1	1	1	1
B	1.5	10,000	NA	14	16	16	15	13	2
C	3.5	2,000,000	1	4	3	1	1	1	NA
D	7.1	2,000,000	1	6	3	10	1	1	11
E	7.3	1,000,000	11	14	16	12	15	13	9
F	7.8	2,100,000	1	4	3	1	1	1	NA
G	7.9	3,900,000	1	4	NA	NA	NA	1	NA
H	8.1	3,880,000	11	14	16	12	15	13	9
I	8.3	6,600,000	NA[b]	NA	NA	NA	NA	NA	NA
J	8.5	2,000,000	NA[c]	NA	NA	NA	NA	NA	NA
K	8.8	7,400,000	1	4	3	1	1	1	1
L	9.7	5,600,000	NA[d]	NA	NA	NA	NA	NA	NA
M	9.7	2,000,000	11	14	16	12	15	13	9
N	10.3	1,000,000	1	4	3	1	1	1	1
O	11.5	4,880,000	NA[e]	NA	NA	NA	NA	NA	NA

Abbreviations: CFU, colony-forming units; NA, not available; WCT, water cooling tower
[a] Results shown are for the WCT sample with a positive quantifiable *Legionella* culture on which sequence-based typing analysis was performed; some WCTs had more than one positive quantifiable *Legionella* culture
[b] Isolate was destroyed by the commercial laboratory, in contravention of the provincial regulation that requires all *Legionella* isolates from WCT with levels of 1,000,000 CFUs/L or above to be kept for at least three months
[c] Isolate could not be analyzed due to contamination
[d] Isolate was not sent by the commercial laboratory to the provincial public health laboratory as required by public health; presumed destroyed or lost
[e] Upon reanalysis at the provincial public health laboratory, the isolate was found to be serogroup 2–15 instead of 1; therefore typing was not performed

(15 samples) and August 13–14 (19 samples) either tested negative (25 samples) or had *L. pneumophila* levels below the limit of quantification (9 samples) by qPCR.

Sequence-based typing of clinical and environmental specimens

In total, five clinical isolates were available for typing (**Table 4**); all sequenced alleles matched, suggesting a common source. Four cases had six or seven sequenced alleles, and all sequenced alleles matched each other; two cases from the acute care hospital, one from the retirement home, the other from the

Table 4: Results from sequence-based typing of clinical isolates

Case ID	Exposure setting	Sequence-based typing results						
		flaA	pilE	asd	mip	mompS	proA	neuA
3	Private home	NA	9	2	5	3	20	15
10	Acute care hospital	NA	9	2	5	3	20	15
9	Acute care hospital (same floor)	12	9	2	5	3	20	NA
11	Cancer care home	12	NA	NA	NA	3	NA	NA
12	Retirement home	12	9	2	5	3	20	15

Abbreviation: NA, not available

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community. Only two alleles from the cancer care home case could be sequenced; both matched all other cases. The sequence type for the only fully typed case (Table 4, Case ID 12) was a new type, ST2858, in the EWGLI database. Typing results from the WCTs were not a match to the clinical isolates (Table 3).

Discussion

We investigated a spatiotemporal cluster of 14 *L. pneumophila* serogroup 1 cases reported over a 12-week period from June to August 2019, in Montréal. The outbreak was initially detected through routine daily automated geospatial cluster analysis of reportable disease data. Our epidemiologic investigation identified that outbreak cases tended to be younger, have more comorbidities including compromised immunity or suppression, as compared to non-outbreak cases. No common exposure was identified other than place of residence. Two sub-clusters were identified: three cases resided in the same retirement home and four had been hospitalized on the same acute care hospital floor for their entire incubation period. Typing was performed for five cases; results suggested a common source for all cases. The outbreak was declared over in mid-October, but an environmental source was never identified.

The outbreak investigation benefited from access to monthly *L. pneumophila* monitoring results for all WCTs in the provincial registry and rapid sampling WCT sampling and decontamination (through public health orders). Whereas the outbreak was eventually controlled, our extensive environmental investigations did not identify a source. One potential explanation is that a WCT may harbour multiple *L. pneumophila* serogroups concurrently (15,16) that may change rapidly over time (11) (e.g. between the case's exposure and the sampling of the WCT).

It is not uncommon to fail to identify the source of a *L. pneumophila* outbreak. The Centers for Disease Control and Prevention (CDC) did not find a source for 11 of 17 *L. pneumophila* serogroup 1 outbreaks associated with environmental or undetermined exposures to water in 2013–2014 (17). Similarly, in the United Kingdom, the source was identified in less than 50% of *Legionella* outbreaks (18,19). Recent research suggests that sequence-based typing is insufficient to discriminate between some *L. pneumophila* serogroup 1 (15,20); therefore, it is possible that our outbreak cases were not infected with the same *L. pneumophila* serogroup 1; however, this issue has not been reported for *L. pneumophila* serogroup 1 ST2858.

There were several key challenges in attempting to identify the source of this outbreak. Clinical isolates (i.e. sputum cultures) were available for only a quarter of all cases, thereby limiting our ability to assess which were linked to the outbreak and muddying the search for a common source. The unavailability of environmental isolates from WCTs with *L. pneumophila* monitoring results below 1,000,000 CFU/L, because laboratories are not legally mandated to retain them, also hampered our investigation. Those WCTs had to be resampled, often a few weeks after the initial positive result, sometimes after corrective action, thereby decreasing the probability of re-isolating the same *L. pneumophila* that had been present during the cases' incubation period. There is evidence of *Legionella* outbreaks associated with WCT concentrations of *L. pneumophila* below 1,000,000 CFU/L: a systematic review of all *Legionella* outbreaks attributed to WCTs in 2001–2012 found *Legionella* concentrations below 1,000,000 CFU/L in 4/19 outbreaks (21). A 2017 legionellosis outbreak in the *Mauricie-et-Centre-du-Québec* health region was genetically linked to a WCT that showed "interfering flora" on routine *Legionella* monitoring and had a *Legionella* concentration of 630,000 CFU/L on resampling (1). Given that 11 of the 14 patients in our outbreak were immunocompromised or immunosuppressed, it is possible that the source was a WCT with *L. pneumophila* serogroup 1 levels below 1,000,000 CFU/L.

Another important challenge was the lack of comprehensive databases on potential sources of water aerosolization other than WCTs, for example, decorative water features on public and private properties, public and private construction sites and large-scale irrigation systems. As a result, we could have overlooked a potential source. Also, whereas the RBQ estimates that nearly all WCTs in QC are registered, WCTs on federal buildings are monitored for *L. pneumophila* by a federal agency and results are not reported to the RBQ.

Finally, the provincial sampling protocol involves collecting a single 1 L water sample per WCT, under both routine and outbreak conditions. In contrast, the CDC recommends obtaining five 1 L water samples and three biofilm swabs (from specific areas) per WCT as part of an outbreak investigation (22). Following the CDC's WCT sampling protocol would have likely increased the probability of detecting *L. pneumophila* serogroup 1 in sampled WCTs, thereby increasing the probability of identifying the source of our outbreak.

Conclusion

This report describes a community-based outbreak of *L. pneumophila* serogroup 1 with retirement home and acute care hospital sub-clusters. Whereas typing of clinical isolates suggested a common environmental source, our investigation failed to identify it. Future outbreak investigations could benefit from the availability of more clinical isolates for typing, perhaps adding NAAT to culture (e.g. when antibiotics have already been started); local registries of water features other than WCTs (e.g. fountains) that could potentially aerosolize *L. pneumophila*; ongoing access to all routine WCT monitoring results, rather than public health only being notified of results above a threshold; and access to all recent *L. pneumophila* isolates obtained through routine WCT monitoring (regardless of concentration) for typing. Research is needed to update and summarize *L. pneumophila* environmental sources that have been linked

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to cases or outbreaks, as well as to identify *L. pneumophila* thresholds for action that account for the possibility that immunocompromised or immunosuppressed persons may be infected by lower concentrations of bacteria.

Authors' statement

GC co-led the epidemiologic investigation and is the primary author of the manuscript
JB and FL led the environmental investigation, contributed to writing the sections on the environmental investigation and provided feedback on the manuscript
CL oversaw the analyses conducted at the provincial public health laboratory and provided feedback on the manuscript
PAP co-led the epidemiologic investigation and provided feedback on the manuscript
DK oversaw the environmental investigation and provided feedback on the manuscript
EL oversaw the epidemiologic investigation and provided feedback on the manuscript

Competing interests

None.

Acknowledgements

The authors would like to thank all members of the teams at the Direction régionale de santé publique de Montréal's Prévention et contrôle des maladies infectieuses (PCMI) and Environnement urbain et saines habitudes de vie (EUSHV), and Activités courantes et vigie sanitaire (ACVS) who contributed to this outbreak investigation. The authors would also like to acknowledge the Laboratoire de santé publique du Québec (LSPQ), the Centre d'expertise en analyses environnementales du Québec (CEAEQ), the Régie du bâtiment du Québec (RBQ), the hospital infection prevention and control team, and the retirement home administrators involved in this outbreak investigation.

Funding

All authors received salary support from their respective organizations to complete this work.

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OVERVIEW

The epidemiology of cryptosporidiosis in Ontario, Canada following the introduction of PCR testing in 2018

Karen Johnson[1], Palvasha Thayani[2], Bryna Warshawsky[1,3], Yvonne Whitfield[1], Jennifer Pritchard[1], Michelle Murti[1,4]*

Abstract

Background: Cryptosporidiosis is reportable in Ontario, Canada. Detection by polymerase chain reaction (PCR) was introduced by a large community-based laboratory in August 2017, and in 2018, the incidence of reported cryptosporidiosis doubled compared to 2012–2016.

Methods: We assessed cases reported in 2018 for epidemiologic changes since the introduction of PCR testing.

Results: No outbreaks were identified in 2018, and 48% of cases were detected by PCR, suggesting that the observed increase was likely the result of PCR's higher sensitivity compared with previous detection method. From the pre to post-PCR periods, the proportion of female cases increased significantly, due mainly to cases diagnosed by PCR. A significant increase in mean age was also observed among cases diagnosed by microscopy and/or PCR in the post-PCR period.

Conclusion: Our findings highlight the importance of assessing diagnostic methods when evaluating changes in reported rates. The observed changes in incidence will require ongoing monitoring and may require shorter baseline periods for aberration detection.

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Suggested citation: Johnson KO, Thayani P, Warshawsky B, Whitfield Y, Pritchard J, Murti M. The epidemiology of cryptosporidiosis in Ontario, Canada following the introduction of PCR testing in 2018. Can Commun Dis Rep 2020;46(7/8):227–30. https://doi.org/10.14745/ccdr.v46i78a02

Keywords: *Cryptosporidium*, cryptosporidiosis, surveillance, PCR, polymerase chain reaction, epidemiology, outbreak detection

Introduction

Cryptosporidiosis is a diarrheal disease transmitted through fecal–oral contact with infected persons or animals. Although the mode of transmission varies, infection is most acquired through ingestion of drinking or recreational water that has been contaminated with *Cryptosporidium* oocysts (1). Cryptosporidiosis is traditionally diagnosed by microscopic examination of stool specimens and/or enzyme immunoassays for detection of antigens to *Cryptosporidium* spp. However, molecular methods including polymerase chain reaction (PCR) are increasingly used (2,3). In Ontario, Canada, hospital laboratories, the provincial public health laboratory and privately operated community laboratories conduct diagnostic testing for cryptosporidiosis. Privately operated community laboratories diagnose the majority of cases reported. All laboratory-confirmed cases of cryptosporidiosis are reportable in Ontario (4), and reported cases are followed up by local boards of health that collect and report case information centrally to provincial public health officials through the integrated Public Health Information System (iPHIS).

Microscopy has been the main method of detection for cryptosporidiosis in Ontario. In August 2017, a large community-based laboratory with collection centres across the province adopted multiplex PCR testing (5). Recent studies have shown the sensitivity of microscopy to range from 52% to 56% compared to PCR, which has a sensitivity of 100% (6,7).

In this article, we describe our investigation of an increase in reported cryptosporidiosis cases in 2018 with the aim of assessing the magnitude of the increase, determining the role

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of PCR testing in the increase and identifying if any shifts had occurred in the epidemiology of cryptosporidiosis since the implementation of PCR testing.

Methods

We conducted this assessment by comparing demographic, risk factor and outcome data from iPHIS for 2018 (the first full year following implementation of PCR testing) with the pre-PCR period of 2012–2016.

We extracted information on age, sex, outcome (hospitalization or death), reported symptoms, reporting laboratory (i.e. community based, hospital or public health) and method of diagnosis [i.e. PCR, microscopy, enzyme immunoassay (EIA) and culture-bacterial] from iPHIS for cryptosporidiosis cases with episode dates from January 1, 2012 to December 31, 2016 (pre-PCR) and from January 1 to December 31, 2018 (post-PCR).

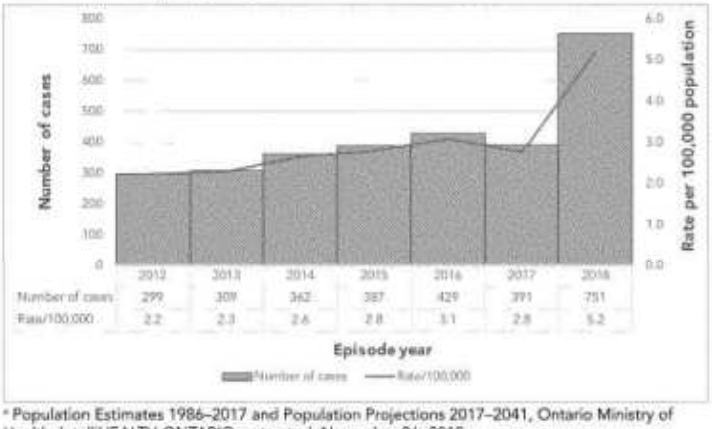
Cases with no diagnostic data, cases diagnosed by PCR in the pre-PCR period and cases that had "culture-bacterial" (which reflect data entry errors) as the method of detection were excluded from all analyses except for overall case counts and rates. Social or behavioural risk factors, including history of travel outside the province, foodborne and waterborne exposures, and animal and person-to-person contact, for cases with episode dates in 2018, were also analyzed to determine whether there were any previously unrecognized outbreaks. All analyses were performed using the statistical package SAS Enterprise Guide version 7.1 ($p<0.05$ considered statistically significant).

Results

Reported cases of cryptosporidiosis increased annually from 299 in 2012 to 429 in 2016, decreased to 391 in 2017 and then increased to 751 in 2018 (**Figure 1**). The annual rate of cryptosporidiosis in Ontario was 2.6 per 100,000 from 2012 to 2016 and 5.2 per 100,000 in 2018 ($p<0.001$). Based on 1,743 cases in the more detailed analysis, detection by PCR accounted for 48% of cryptosporidiosis cases reported in 2018, while detection by microscopy decreased from 99.8% in 2012–2016 to 52% in 2018 ($p<0.001$); EIA was the method of detection for three cases reported during the pre-PCR period (0.2%).

Statistically significant overall and sex-specific increases in mean ages were also observed; the increases in the post-PCR period occurred among cases diagnosed by microscopy and by PCR (**Table 1**). Overall, the proportion of cases among females increased from 48.5% in the pre-PCR period to 55.4% in the post-PCR period ($p<0.009$). Stratification of the post-PCR period showed that this shift in proportion from the pre-PCR period was driven by cases diagnosed by PCR (60.8% in the post-PCR period, $p<0.001$) as the proportion of female cases diagnosed

Figure 1: Number and incidence rate for all confirmed cases of cryptosporidiosis reported, Ontario, Canada, 2012–2018 (n=2,928)[a]



	2012	2013	2014	2015	2016	2017	2018
Number of cases	299	309	362	387	429	391	751
Rate/100,000	2.2	2.3	2.6	2.8	3.1	2.8	5.2

[a] Population Estimates 1986–2017 and Population Projections 2017–2041, Ontario Ministry of Health, IntelliHEALTH ONTARIO, extracted: November 26, 2019

by microscopy in the post-PCR period (50.4%) did not vary significantly from the pre-PCR period (48.5%, $p<0.580$) (Table 1).

From the pre to the post-PCR period, the proportion of hospitalized cases decreased from 5.5% to 2.1% ($p<0.002$). No deaths were recorded in either time period. Method of testing was not related to symptom status, although the proportion of asymptomatic cases was slightly higher among those diagnosed by PCR (2.2%) and microscopy (1.3%) in the post-PCR period relative to the pre-PCR period (0.8%).

Based on the assessed risk factors, no commonalities were reported at the provincial level that suggested the occurrence of any outbreaks among non-travel cases in 2018, or within the health units that had identified localized increases above their usual summer peak in incidence.

Conclusion

Our investigation identified a two-fold increase in the incidence of cryptosporidiosis cases in 2018, the first full year after the introduction of PCR testing in August 2017, compared to the pre-PCR period of 2012–2016. However, it remains unclear why the number of cases reported in 2017 decreased despite the introduction of PCR in that year and a gradually increasing trend in the previous five years. As only positive laboratory results are reportable in Ontario, we were not able to assess if the increase in 2018 was due to an increase in the number of cases, an increase in the number of tests ordered or an increase in positivity owing to PCR's higher sensitivity compared with previous detection method. Our investigation of the increase in 2018 also did not identify any common social and behavioural risk factors among domestic cases that were indicative of an outbreak. During the period of increase, clinical indications for testing and surveillance criteria for defining and reporting cases did not change, nor did healthcare providers have the option to

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Table 1: Cryptosporidiosis cases reported during the pre-PCR period (2012–2016) compared to cases reported in 2018, overall and stratified by diagnostic method (n=1,743)[a]

Case characteristics	Pre-PCR period (2012–2016)		Post-PCR period (2018)[b]							
	Microscopy (n=1,209) and EIA (n=3)		PCR			Microscopy			Microscopy and PCR	
			n=255		p value[c]	n=276		p value[c]	n=531	p value[c]
Diagnosed (%)	Microscopy (99.8%), EIA (0.2%)		48.0%		–	52%		–	100%	–
Mean age (years)										
Female	23.3		27.3		<0.005	28.4		<0.001	27.8	<0.001
Male	20.9		26.4		<0.002	24.9		<0.011	25.5	<0.001
Total[d]	22.1		26.9		<0.001	26.6		<0.001	26.8	<0.001
Sex, n (%)[e]										
Female	588	(48.5)	155	(60.8)	<0.001	139	(50.4)	<0.580	294	(55.4) <0.009
Male	620	(51.2)	100	(39.2)	<0.001	136	(49.3)	<0.573	236	(44.4) <0.010
Hospitalized, n (%)	67	(5.5)	4	(1.6)	<0.008	7	(2.5)	<0.040	11	(2.1) <0.001
Symptom status[f]										
Asymptomatic, n (%)	9	(0.8)	5	(2.2)	<0.084	3	(1.3)	<0.461	8	(1.7) <0.129

Abbreviations: EIA, enzyme immunoassay; PCR, polymerase chain reaction; -, no data

[a] Excludes cases diagnosed by PCR in the pre-PCR period (n=7) and cases with no laboratory values or where the diagnostic method was reported as "culture-bacterial" (an inappropriate method of detection that was selected in error during data entry) (n=787)

[b] No cases were diagnosed by EIA in 2018

[c] P values based on appropriate tests for proportions (Pearson chi-square and Fisher exact test) and means (*t*-test). The *p* values indicate the probability of finding the observed values for the comparisons between the combined methods of detection in the pre-PCR period and the post-PCR period (PCR, microscopy and PCR and microscopy combined)

[d] Excludes cases where sex was reported as "other" or "unknown"

[e] Excludes cases with no data on symptoms and cases with symptoms that were classified as not clinically compatible with cryptosporidiosis (e.g. cough)

specify their preferred diagnostic method (e.g. microscopy, EIA or PCR) when ordering tests. Given these factors, it is possible that the increase in 2018 resulted, at least partially, from PCR's higher sensitivity, which resulted in the detection of cases that would have otherwise remained undiagnosed by microscopy or EIA.

With the increase in the reported rate of cryptosporidiosis, there was also an increase in the proportion of female cases in 2018, driven by PCR diagnoses. One possible hypothesis is that the baseline test positivity rate for females was lower compared to males and subsequently more affected by the higher sensitivity of PCR testing. In contrast, the increase in mean age among cases diagnosed by both PCR and microscopy in 2018 may reflect an underlying shift in the age distribution of persons tested in 2018 compared to 2012–2016. We would require data on the age and sex of persons that submitted specimens for testing, testing volumes and positivity rates to fully assess these changes in the demographics of cryptosporidiosis cases.

The shift towards fewer hospitalized and more asymptomatic cases after the introduction of PCR testing reflects PCR's higher sensitivity and use in community laboratories that test non-hospitalized patients. Similar trends among microscopy-detected cases were also observed, suggesting that factors other than the introduction of PCR testing may have influenced the shifts in hospital and symptom status in 2018. However, given the small proportions of cases overall that were hospitalized or asymptomatic, caution must be exercised in drawing conclusions from these limited post-PCR data.

Our investigation demonstrated that the traditional approach to examining incidence over time for trends and outbreak detection must be coupled with a review of other data elements such as diagnostic methods and risk factor information, which can indicate whether increases are artifacts, due to increases in sporadic cases or attributable to a specific source. We anticipate that the adoption of PCR testing for diagnosing cryptosporidiosis will occur at different times by the various diagnostic laboratories in Ontario, resulting in staggered increases in incidence. These changes will require continuous reassessment of baseline values for accurate interpretation of trends for aberration detection and timely outbreak detection. With time, we expect the emergence of a more stable and long-standing baseline at a higher incidence rate due to the more widespread use of PCR. As our investigation reflects one year of PCR testing, analysis of additional years of data is required to understand the clinical and public health relevance of cases detected by this method.

Authors' statement

KJ — Data analysis, Writing – review & editing
PT — Data analysis, Writing – review & editing
BW — Data review, Writing – review & editing

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YW — Data review, Writing – review & editing
JP — Project administration, Writing – review & editing
MM — Writing – original draft, Writing – review & editing

Competing interests

None.

Funding

This work was supported by Public Health Ontario.

Acknowledgements

We thank L Friedman from Public Health Ontario for providing copy editing and reference management.

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RAPID COMMUNICATION

COVID-19 and the increasing need for sex-disaggregated mortality data in Canada and worldwide

Amanda Lien[1], Rojiemiahd Edjoc[1]*, Nicole Atchessi[1], Christine Abalos[1], Imran Gabrani-Juma[1], Marianne Heisz[1]

Abstract

In countries most impacted by coronavirus disease (COVID-19), such as Italy and China, surveillance reveals that the number of deaths differ by sex. Preliminary data suggest that while the distributions of cases vary by sex, men represent the larger proportion of deaths in these countries. Analyses of deaths can indicate differential disease progression between men and women more robustly than analyses of cases, as the former are less susceptible to biases of underreporting and bottlenecks in testing. Canada has an enormous opportunity to apply its sex-specific mortality data to conduct comprehensive health and medical research that captures sex-based differences in manifestation of the disease to improve outcomes and prevention methods. During the ongoing pandemic, it is difficult for complete and wholly accurate data of all COVID-19 deaths to be obtained when healthcare and public health personnel are operating at full capacity. However, it is crucial that efforts continue to be made to capture this information and make it accessible, as it can also be applied to inform implementation of more effective and equitable public health and clinical strategies, such as the dissemination of targeted health communication materials and therapy.

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Suggested citation: Lien A, Edjoc R, Atchessi N, Abalos C, Gabrani-Juma I, Heisz M. COVID-19 and the increasing need for sex-disaggregated mortality data in Canada and worldwide. Can Commun Dis Rep 2020;46(7/8):231–5. https://doi.org/10.14745/ccdr.v46i78a03

Keywords: COVID-19, coronavirus, sex, gender, infectious disease

Introduction

Many countries, including Canada, have implemented substantial control measures such as physical distancing and travel restrictions to reduce the spread of coronavirus disease (COVID-19), a novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) disease that is highly transmissible through droplets and direct contact (1–3). As of June 10, there were approximately 7.27 million cases of COVID-19 worldwide and 412,013 deaths (5). In Canada, there were 96,653 confirmed cases and 7,897 deaths had occurred as of June 9, 2020 (6).

During the 2002–2003 outbreak of severe acute respiratory syndrome (SARS), a disease also caused by a type of coronavirus, sex-based mortality data indicated that men had a higher case fatality rate than women (7,8). Other studies have also established that sex is linked with response to infectious diseases (9,10). Based on studies of SARS and other epidemic-prone infectious diseases (11), the World Health Organization has encouraged the implementation of sex-based health communication, promotion and primary care strategies.

Early sex-based mortality data from the ongoing COVID-19 pandemic indicates that males account for more COVID-19 related deaths than do females in nearly every country for which such data are available (12). Despite the preliminary observations suggesting that sex plays a role in disease outcome and severity, few countries collect complete sex-disaggregated data on deaths.

Data on COVID-19 cases can be subject to possible biases in symptom reporting and selection bias towards more severe manifestations of the illness due to bottlenecks in testing (13). In contrast, data on COVID-19 deaths are more robust. For instance, in April 2020 the Ontario Ministry of Health guidelines stated that high-risk individuals such as health care workers and persons living and working in congregate living institutions and their close contacts should be tested if displaying symptoms (14). With testing resource availability a likely barrier and women more likely to report bodily symptoms than men (15–18), there may be

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a sex-based bias that can result in more men failing to seek or receive adequate care.

Gathering sex-disaggregated mortality data is crucial to providing a better understanding of sex-based disparities in COVID-19 outcome severity and mortality risk (19). Knowing these risks, in turn, can inform more comprehensive research and equitable and effective public health interventions such as targeted health communication and clinical care. Focusing on capturing these data is a feasible start to creating a national dataset that contains disaggregated sex and gender data. This review focuses on the need to gather sex-based data, which can provide insight into the role that biological differences may play in mortality risk. However, gathering gender-based data is also necessary to determine the role of gender-based inequities, norms, and behaviours in mortality risk. Gathering sex-disaggregated mortality data could begin to provide even greater insight into differential disease progression that is associated with behaviours linked with gender norms (12,20).

Current situation

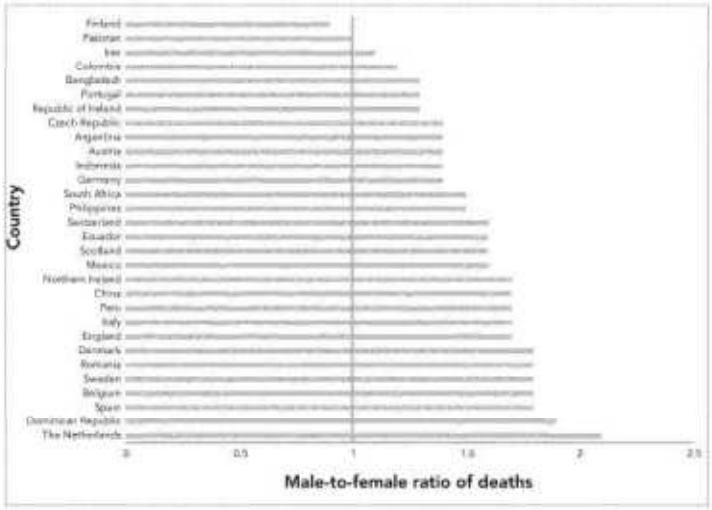
The role of sex in COVID-19 mortality risk

Women form a large proportion of the health workforce and are at greater risk of exposure to SARS-CoV-2 (21). This is reflected in their greater representation among confirmed COVID-19 cases in Canada (6). Unlike in most other countries, women also represent a larger proportion of deaths among confirmed cases. On the global scale, early studies suggested sex-based immunological differences as a possible partial explanation for the greater number of male deaths related to COVID-19 (22,23). Various studies based on populations in China found that the presence of certain medical conditions, such as those for which smoking is a risk factor, which disproportionately affect men (24), may increase the risk of severe COVID-19 illness and outcomes (25,26). Studies in populations with different ethnic and genetic backgrounds are needed to better understand sex-based differences in the expression of angiotensin-converting enzyme 2 (ACE2)—which has increased expression with smoking and is the receptor of SARS-CoV-2—and how this relates to COVID-19 mortality risk (27). The observation that Canada's mortality data does not follow the global trend of men having greater mortality risk may be attributable to other factors specific to Canada. For instance, although sex may play a role, other demographic variables such as age and other genetic factors may also contribute to mortality risk. The interplay between these factors in affecting COVID-19 mortality risk is unknown. In terms of responses to COVID-19, some studies using sex-based case data found major public health interventions such as travel restrictions and social distancing to be associated with equally improved control of the outbreak among both sexes (28,29). However, the effects of public health interventions and policy on mortality risk by sex is unknown.

Trends in sex-disaggregated mortality data

As of June 10, 2020, sex-disaggregated data for COVID-19-related deaths were available for various countries (20). While the male-to-female ratio of confirmed cases varied by country, males represented a larger proportion of deaths among confirmed cases in all but two of these countries (**Figure 1**). Meanwhile, there were several highly affected countries for which the ratio of male-to-female deaths among confirmed COVID-19 cases could not be confirmed, including the United States and France.

Figure 1: Male-to-female ratio of deaths among confirmed cases of COVID-19 in the thirty countries with the most deaths outside of Canada, where the data were available, June 10, 2020



Because sex-disaggregated mortality data on the global scale is somewhat incomplete, establishing the role that sex may play in COVID-19 mortality risk is challenging. The Government of Canada's data suggest that Canada's distribution of deaths by sex does not follow the trend that has been observed in other highly affected countries (6). Among the deaths reported as of June 9, 2020, the male-to-female ratio of deaths among confirmed cases was 0.85. This observation may be attributable to factors such as sex-based age distribution, long-term care facility resident distribution, and frontline health workforce distribution (30,31). It also warrants exploration of possible sex-based disparities in the Canadian context pertaining to areas such as public health interventions, healthcare access, and disease progression.

The Public Health Agency of Canada houses a dataset that includes sex information of COVID-19 deaths; this dataset is made available publicly in an aggregated format (6). The disaggregated line list is obtained from the provinces and territories but may be missing or lagging information due not only to challenges in data collection as the result of the pandemic but also to already existing data collection issues

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exacerbated by the pandemic. This obstacle may prevent complete and up-to-date information from being recorded and passed on to the federal government for timely dissemination. Nevertheless, it is important that this information continue to be captured as best as possible as it can inform research and the public health response. Furthermore, COVID-19 cases admitted to the intensive care unit (ICU) experienced longer durations between symptom onset to hospitalization than non-ICU cases (32). Therefore, health promotion efforts that encourage men to use health services earlier and more effectively may be a practical intervention to implement.

Recommendations

Despite local, provincial and national-level institutions operating at full capacity and the challenges that might come with resource and personnel availability in some regions during a pandemic, it is recommended that efforts continue to be made to capture sex-disaggregated COVID-19 mortality data in Canada and worldwide. An effective collaboration between provinces and government would also be a catalyst for the achievement of this goal in Canada. We acknowledge the efforts being made by Statistics Canada, the Public Health Agency of Canada, Health Canada and other federal partners, working closely with provinces, territories and coroners to provide more comprehensive and timely death statistics. Sex-disaggregated data would allow for sex-based analyses to be incorporated into research pertaining to the health behaviours and outcomes surrounding COVID-19 (33) that serve to inform clinical care and health communication and to reveal how public health interventions differentially affect men and women. In terms of clinical care, improved outcomes such as reduced mortality could be seen with sex-based medical interventions if disease progression differs between men and women. In terms of public health interventions, implementing strategies such as sex-based, targeted health communication messages could be more effective in instilling prevention principles among male and female audiences. In order to gain a more comprehensive and clearer understanding of how sex and COVID-19 mortality are related, it is recommended that all countries strive to collect sex-disaggregated mortality data and make these data accessible. While we describe the rationale and advocate for the capture of comprehensive sex-disaggregated data, we have not explored the issue of gender. It is also important that gender-disaggregated data be captured as it can reveal the role of gender-based inequities, norms, and behaviours in COVID-19 mortality risk.

Conclusion

Early data from the COVID-19 pandemic suggest that men represent the larger proportion of COVID-19 deaths in most countries. Currently, Canadian response to the COVID-19 pandemic has included policies and public health efforts that consider various aspects of SARS-CoV-2, such as its infectivity and routes of transmission. However, there is an opportunity to curb the number COVID-19-related deaths and severe outcomes by incorporating the role of sex in mortality risk into more comprehensive and relevant research and to develop a more effective response that can include targeted health communication and clinical care. It is therefore essential that these data continue to be collected, made accessible and applied in Canada and other affected countries in a timely manner during the ongoing COVID-19 pandemic.

Authors' statement

AL — Methodology, investigation, writing – original draft
RE — Conceptualization, writing – review and editing, supervision
NA — Writing – review and editing
CA — Writing – review and editing
IGJ — Writing – review and editing
MH — Writing – review and editing

Competing interests

None.

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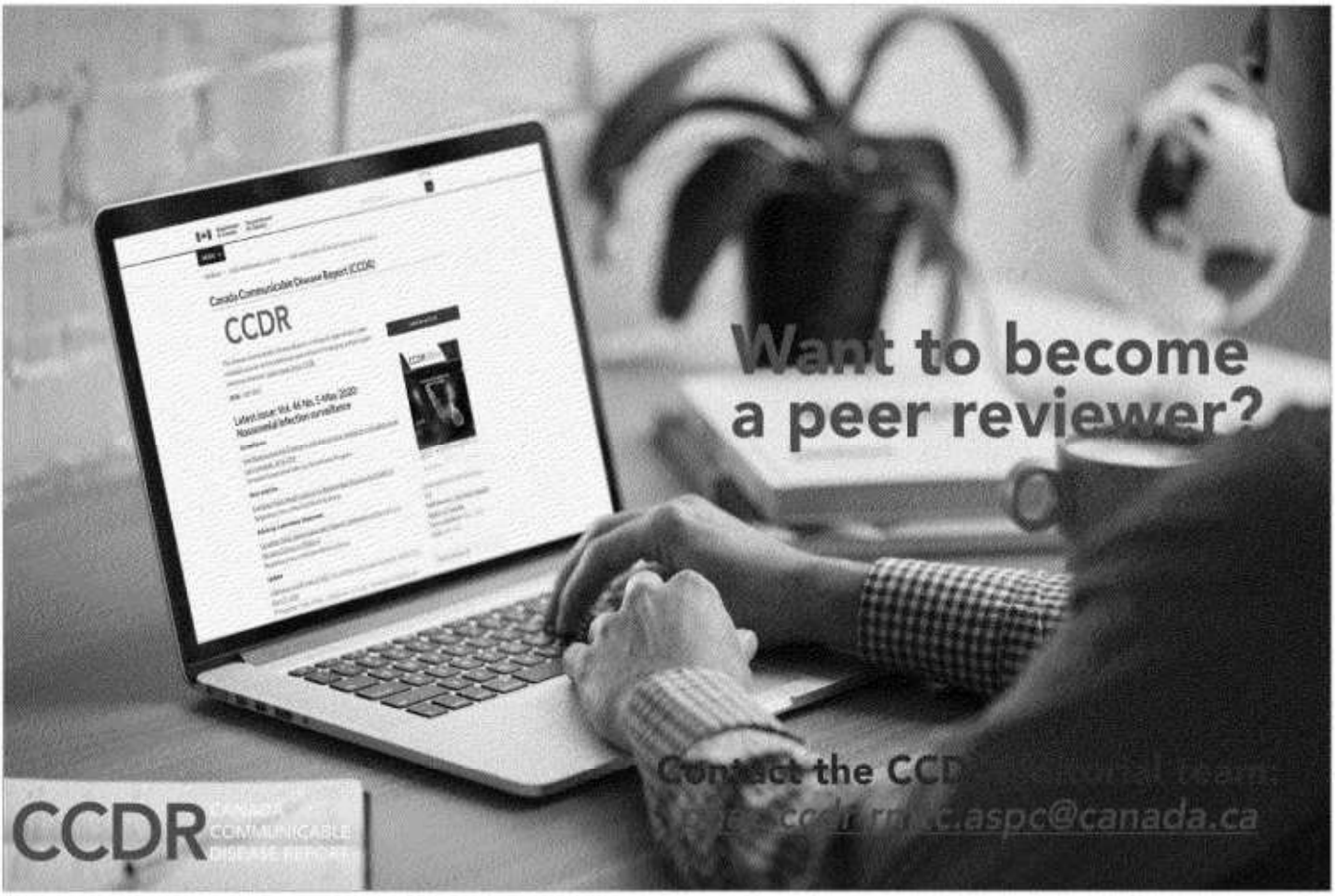

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A retrospective analysis of the start of the COVID-19 epidemic in Canada, January 15–March 12, 2020

Public Health Agency of Canada COVID-19 Surveillance and Epidemiology Team

Abstract

We describe the epidemiology of COVID-19 at the start of Canada's epidemic from January 1 to March 12, 2020, before governments at all levels implemented aggressive community-based public health measures. During this time, 153 laboratory-confirmed cases were reported in Canada. Due to delays inherent in the diagnosis and reporting process, these cases represented a small subset of the 1,360 confirmed cases subsequently reported, whose symptom onset occurred on or before March 12. More than half (57.8%) of these 1,360 cases had a history of international travel or were linked to a case that had travelled, most commonly from countries where few cases had been reported at that time. Community transmission, marked by cases that could not be traced back to another case, was first noted on February 20 and increased steadily thereafter. This descriptive analysis indicates that COVID-19 was spreading internationally and in Canada more broadly than was initially detected by surveillance systems from January to mid-March 2020. To limit the impact of future waves, an expanded surveillance system is now being implemented with multiple data streams to provide a more complete picture of the epidemic, including early signals of cases and clusters. Improved access to laboratory testing and expanded contact tracing are critical elements to detect and isolate cases early, including those with mild symptoms.

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Suggested citation: Public Health Agency of Canada COVID-19 Surveillance and Epidemiology Team. A retrospective analysis of the start of the COVID-19 epidemic in Canada, January 15–March 12, 2020. Can Commun Dis Rep 2020;46(7/8):236–41. https://doi.org/10.14745/ccdr.v46i78a04
Keywords: epidemic, COVID-19, Canada, retrospective analysis, epidemiology

Introduction

Following reports of severe pneumonia with an unknown etiology in Wuhan, China in December 2019 and subsequent confirmation that these illnesses were caused by a novel coronavirus on January 7, 2020, the federal, provincial, territorial and local governments in Canada implemented enhanced public health surveillance and took progressive public health action to prevent transmission of the disease inside their borders. These efforts included, and were not limited to, activating intergovernmental public health emergency response plans, implementing progressively more restrictive border measures, and establishing and expanding testing capacity. Early efforts focussed on containment at source, in order to slow importation to Canada and prevent spread domestically.

Canada's first imported case was reported on January 25, 2020 but it was not until mid-March that daily case counts started climbing. By June 2, 92,151 cases had been reported across 12 provinces and territories. Though daily case counts were on the decline at the time of writing, the disease continues to spread in some areas and settings, and no vaccine currently exists for this novel coronavirus. Evidence-based public health measures are vital to control the epidemic in Canada. Understanding the early epidemiology of COVID-19 in Canada will inform the strengthening of public health surveillance systems, allow for the implementation of appropriate public health measures, and increase understanding of impacts across different groups (e.g. women and men, different age groups).

This rapid communication describes the epidemiology of COVID-19 in Canada from January 1 to March 12, 2020. March 12, 2020 is significant because this date marks the beginning of aggressive public health measures implemented by federal, provincial and territorial jurisdictions to limit the transmission of COVID-19 (e.g. school closures, closure of non-essential businesses and strict border controls) in Canada.

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Situation

Importation

Based on information received from provinces and territories as of April 17, 2020, 1,360 laboratory-confirmed cases were reported with an illness onset between January 1 and March 12, 2020. Case characteristics are summarised in **Table 1**, including cases by sex and age. During this period, more than half (57.8%) of the cases were related to international travel: 52.2% (n=710) had a history of international travel and 5.6% (n=76) were linked to cases who had travelled. Of the 710 cases with a history of international travel, 703 cases provided specific information on countries visited. More than a third (34.7%) of these cases had transited through or arrived from the United States, and almost 20% had arrived from either the United Kingdom or France (**Table 2**). Notably, only 1.4% of cases had arrived from China even though China was the epicenter of the COVID-19 pandemic throughout January and February (1,2).

Table 1: Characteristics of COVID-19 cases with illness onset from January to March 12, 2020 (N=1,360)

Case characteristics[a]	Frequency	
	n	%
Province/territory		
ON	533	39.2
QC	312	22.9
BC	250	18.4
AB	166	12.2
MB	24	1.8
NS	18	1.3
NB	17	1.3
SK	32	2.4
NL	1	0.1
PE	2	0.2
YT	2	0.2
Repatriated traveller	3	0.2
Gender[b]		
Female	670	49.5
Male	684	50.5
Age group (years)		
0–19	52	3.9
20–39	368	27.8
40–59	510	38.5
60–79	341	25.8
80 and older	53	4.0
Hospitalized (includes ICU)	195	17.5
ICU admissions	81	10.3
Deaths	27	2.5

Abbreviations: AB, Alberta; BC, British Columbia; ICU, intensive care unit; MB, Manitoba; NB, New Brunswick; NL, Newfoundland and Labrador; NS, Nova Scotia; ; ON, Ontario; PE, Prince Edward Island; QC, Quebec; SK, Saskatchewan; YT, Yukon Territory

[a] Missing data for gender (six cases), age (36 cases), hospitalized (246 cases), ICU admissions (573 cases) and deceased (280 cases) were not included in the calculation of percentages

[b] Provinces and territories may define gender differently and some may be referring to biological sex

Table 2: Countries visited by cases of COVID-19 in Canada who reported international travel in 14 days prior to symptom onset, January to March 12, 2020 (N=703)

Country(ies)[a,b]	n	%
United States	244	34.7
United Kingdom	67	9.5
France	64	9.1
International conveyance (cruise)	47	6.7
Germany	45	6.4
Mexico	35	5.0
Iran	34	4.8
Egypt	33	4.7
Spain	29	4.1
Switzerland	24	3.4
Austria	22	3.1
Portugal	21	3.0
Philippines	20	2.8
Cuba	19	2.7
Netherlands	19	2.7
Italy	17	2.4
China	10	1.4

[a] Cases reported all countries visited in 14 days prior to symptom onset, therefore proportions do not total 100%

[b] Of the 710 cases that had travelled internationally, 703 provided information on country

Cases that travelled were categorized according to World Health Organization (WHO) region(s) (3) visited to examine trends over time (**Figure 1**). In the first three weeks of the epidemic (weeks of January 12 to January 26, 2020), there were seven cases and all were either travellers arriving from China (Western Pacific Region) or their close contacts. In early February, four cases were reported with a travel history to the Eastern Mediterranean Region, the European Region and the Americas. Cases with a travel history from these regions occurred despite small numbers of cases being reported within these regions at the time [nine cases in the Eastern Mediterranean Region, 46 cases in the European region and 15 cases in the Americas (excluding Canada)] (4). In the last two weeks of February, a total of 99 cases had transited through or arrived from countries in the Americas. This occurred despite a total of only 65 cases reported within countries of the Americas (excluding Canada) by the end of February (2).

A number of border and travel health measures were implemented during this period (i.e. travel health notices, enhanced symptom screening and public health messaging at ports of entry and requesting arriving international travellers from certain jurisdictions to self-isolate for 14 days). The implementation of measures specific to individual countries was guided, in part, by the number of COVID-19 cases and the type of transmission that was reported by the WHO and individual

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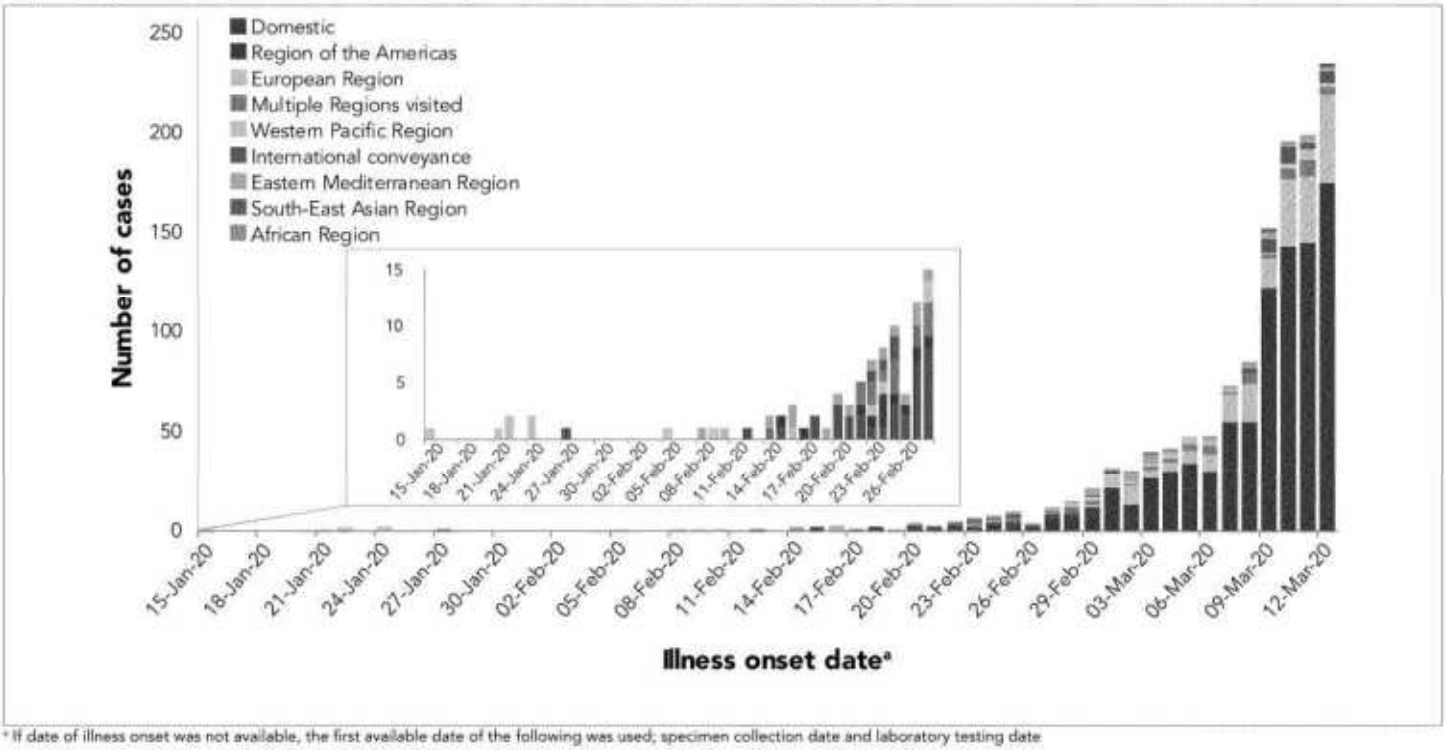
Figure 1: Laboratory-confirmed COVID-19 cases in Canada by date of illness onset and region of travel for cases reporting international travel, January 15 to March 12, 2020 (N=1,275)



[a] If date of illness onset was not available, the first available date of the following was used; specimen collection date and laboratory testing date

countries. The type of transmission was categorized by the WHO as imported cases only, local transmission (transmission occurred within the country with few cases not related to known chains of transmission) or community transmission, defined as the inability to relate a large number of confirmed cases to chains of transmission (2). At the time, with the exception of China, all imported cases to Canada were from countries assessed by WHO as countries with imported cases only or local transmission with no community transmission. In retrospect, it is clear that what was reported globally was only the tip of the iceberg and that the true extent of the global spread of the disease was not known at the time. Using lessons learned from the first wave of COVID-19, additional data sources and indicators will be included in the risk assessments that are used to inform various border and travel health measures such as the timely posting of travel health notices.

Early detection

Early detection of cases is vital to implementing effective public health measures at all jurisdictional levels (local, provincial, territorial and federal). During the start of the epidemic, the median number of days between illness onset and case report date (as noted by local public health) differed significantly by type of exposure ($p<0.05$). Cases linked to international travel and those that were linked with a known case had a slightly lower number of median days between illness onset and reporting compared to cases that could not be linked to a known case (**Table 3**). In other countries, differences have been noted between those whose infections were acquired internationally compared to domestically (5,6). These differences in Canada and elsewhere were likely due to a higher index of suspicion for those with risk factors that were known at the time. The number of days between illness onset and case report date increased over time, as the number of cases that could not be linked to other cases also increased. This delay began to decrease for cases with illness onset in early March (**Figure 2**).

Table 3: Number of days between date of illness onset and case report date (N=727)[a]

Exposure category	n	Median number of days	25th percentile	75th percentile
International travel history	400	9	6	15
Domestically acquired—Linked to a traveller	49	7	5	11.5
Domestically acquired—Linked to a domestic case	134	8	6	14
Domestically acquired—Could not be linked	87	11	10	18
Domestic—Contact information not specified	57	11	8	19

[a] Dates needed to calculate days from illness onset to case report date were missing for 633 (46.5%) cases

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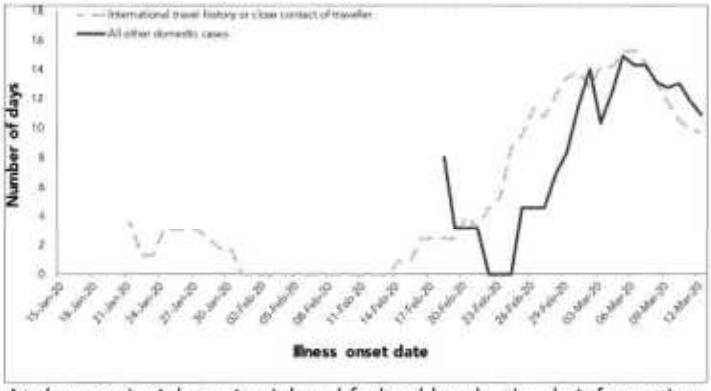
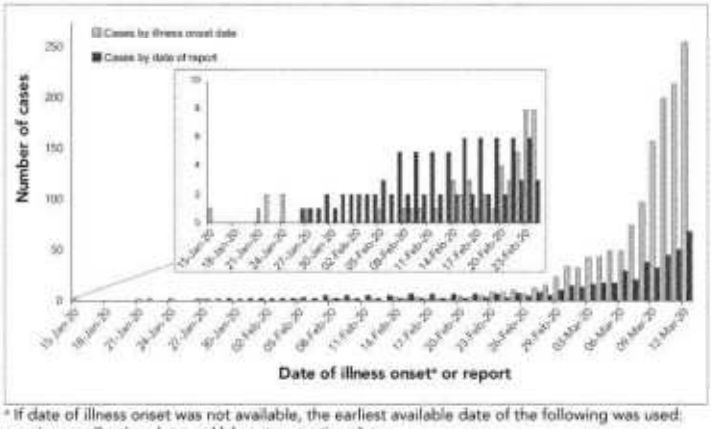
Figure 2: Number of days between illness onset date and case report date (seven day moving average) for COVID-19 cases by exposure, January 15 to March 12, 2020 (N=727)


International travel history or close contact of traveller
All other domestic cases
Number of days
Illness onset date

At the provincial, territorial and federal levels, timely information on cases is needed to develop, implement and evaluate programs and policies to limit transmission. Due to the length of time between illness onset and reporting of cases, provinces and territories had only reported 153 COVID-19 cases as of March 12th, compared to the 1,360 laboratory confirmed cases with actual illness onset during this period (see **Figure 3**). As well, there were likely unreported infections during this period due to limited testing at the time. Results from some countries have indicated the disease was already spreading before the rapid rise in cases was apparent and noted, or in the case of France, even before the first case was reported (7,8).

Figure 3: Number of COVID-19 cases reported daily by provinces and territories compared with those with illness onset[a], January 15 to March 12, 2020



[a] If date of illness onset was not available, the earliest available date of the following was used: specimen collection date and laboratory testing date

At the start of the epidemic, public health surveillance efforts were informed by the surveillance guidance within the Canadian Pandemic Influenza Plan (9). For example, in the initial stages of Canada's epidemic, detailed information was captured on confirmed cases (10) to allow for a description of the epidemiological characteristics of the cases. These efforts were complemented by provincial and territorial efforts, including enhanced surveillance in certain settings (e.g. testing of individuals with respiratory illness in hospitals). Moving forward, a number of complementary data streams will be integrated, to help strengthen COVID-19 monitoring efforts at the national level and detect early signals of increases in cases or clusters or changes in disease severity. These data streams are expected to include provincial and territorial case-based information, federal and provincial public health laboratory data; hospital, emergency and outpatient data, outbreak information and syndromic surveillance through the "Fluwatchers" app (11), among other data sources. The results of future studies will be used to build on the information gleaned from these surveillance activities, and will provide more detailed information on key populations (e.g. the impact of COVID-19 on racialized communities, health care workers, Indigenous communities, and different groups of women, men and gender diverse people).

Onward transmission

In the first four weeks of Canada's outbreak (weeks of January 12 to February 2), 100% of the cases were related to travel (had travelled, or were linked to a traveller). From the week of February 9 to March 12 between 11% and 40% of cases, by week, were domestic cases that could be traced back to another domestic case. On February 23, the first case became ill who could not be linked to another known case (an indicator of community transmission), after which the number of such cases grew steadily (**Figure 4**). Other countries have similarly experienced a short phase of mostly imported cases, followed by the onset and exponential growth in domestically acquired cases (12).

To prevent onward transmission, at the start of the epidemic, guidelines on infection prevention and control and on public health management of cases and contacts were disseminated to facilities and to public health professionals. Canadians were urged to self-monitor for symptoms, to stay at home when ill and practice frequent and meticulous hygienic measures. Nonetheless, community transmission occurred and the number of such cases increased rapidly. This may reflect a number of factors: Canada was still in its influenza season and individuals may not have sought out testing if they had influenza-like symptoms; the contribution of transmission from individuals with mild symptoms who did not seek out testing or who did not qualify for testing given the testing guidance in place at the time; or transmission from individuals who were pre or asymptomatic (13).

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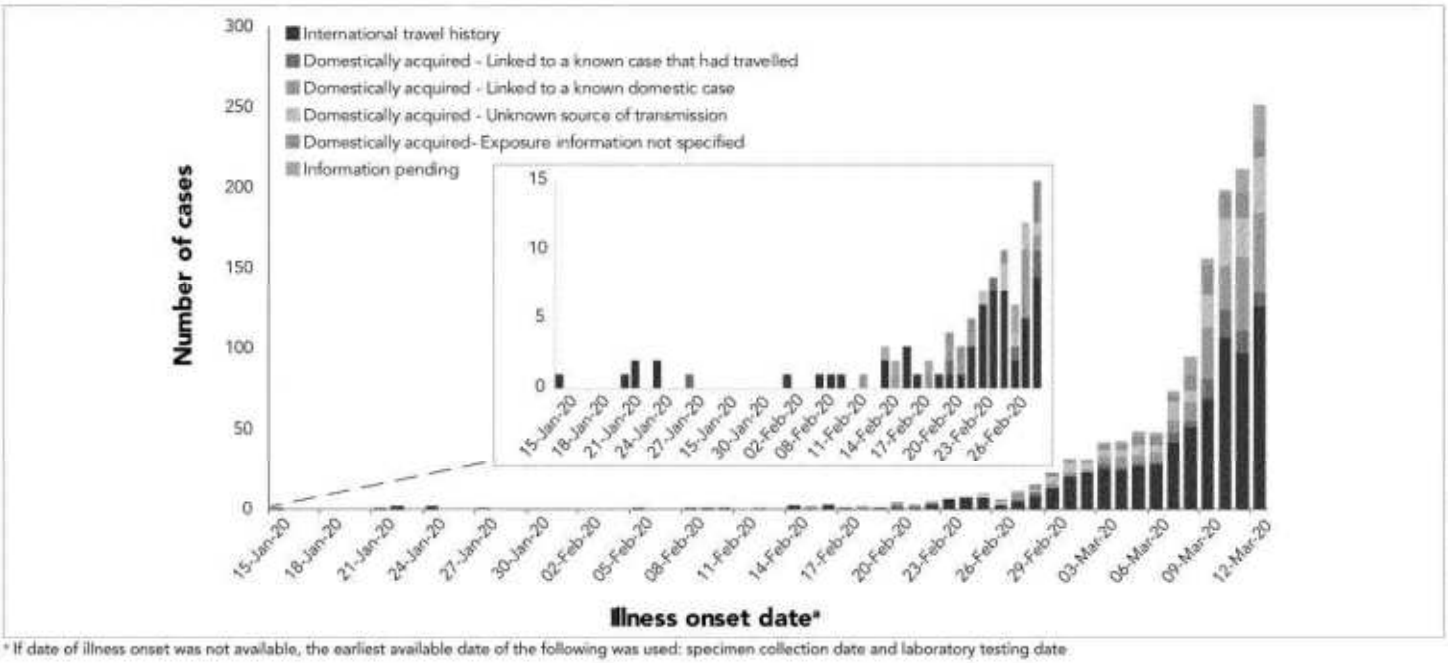
Figure 4: Laboratory-confirmed cases of COVID-19 in Canada by date of illness onset and exposure category, January 15 to March 12, 2020 (N=1,276)


International travel history
Domestically acquired - Linked to a known case that had travelled
Domestically acquired - Linked to a known domestic case
Domestically acquired - Unknown source of transmission
Domestically acquired- Exposure information not specified
Information pending
Number of cases
Illness onset date*

* If date of illness onset was not available, the earliest available date of the following was used: specimen collection date and laboratory testing date

Conclusion

At the start of Canada's epidemic, public health measures to limit the spread of COVID-19 were guided, in part, by the epidemiologic data available at the time. In hindsight, it is clear that these data did not provide the full picture in relation to when and where the disease had spread or how and when individuals were capable of spreading the infection to others. As new evidence emerged to expand our knowledge of COVID-19 epidemiology, our case detection protocols, public health measures and other areas of the COVID-19 response were adapted. Moving forward, surveillance systems will likewise continue to be enhanced through the addition of numerous data streams, which will allow for a more complete picture of the epidemiology of COVID-19 and for the early detection of cases and clusters to inform public health action and improved management of COVID-19 in Canada.

Authors' statement

DP — Conceptualization, original draft, review and editing
LL — Data curation, formal analysis, review and editing
LW — Review and editing
AC — Conceptualization, review and editing
KW — Review and editing
MB — Review and editing
DT — Review and editing
CA — Review and editing
JT — Data curation, formal analysis
JZ — Data curation, formal analysis
JK — Data curation, formal analysis
DM — Review and editing
AN — Review and editing
JP — Review and editing

Competing interests

None.

Acknowledgements

Authors wish to thank provincial and territorial surveillance partners, the National Microbiology Laboratory and provincial public health laboratory partners, and the Health Portfolio Operations Centre's Surveillance Team, Public Health Agency of Canada.

Public Health Agency of Canada COVID-19 Surveillance and Epidemiology Team includes: Dana Paquette, Liza Lee, Lindsay Whitmore, Andrea Currie, Kerri Watkins, Maggie Bryson, Dorcas Taylor, Chris Archibald, Jill Tarasuk, Jingxuan Zhang, Jaskiran Kaur, Diane MacDonald, Alexandra Nunn, Jennifer Pennock.

Funding

This work was supported by Public Health Agency of Canada.

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Effective presentation of data in tables and figures

Patricia Huston[1]

Abstract

The presentation of data in tables and figures is a hallmark of scientific publications. Tables and figures are most effective if they reflect two principles and a number of best practices. The first principle is to use tables and figures to highlight the main findings of a study. The second principle is to choose the appropriate format based on the type of data. Tables are most effective for presenting precise data and multiple outcomes. Figures are most effective for presenting trends over time or comparative values. When constructing a table, different populations are identified in columns and then compared according to variables that are identified in rows. This structure enables comparisons between the different study populations. When constructing figures, the independent variable (such as time) is on the horizontal or x-axis and the dependent or outcome variable is on the vertical or y-axis. Good titles for both tables and figures give a concise description of who, what, where, when and how many. Electronic readers can read tables if there are visible row and column lines and there is a single datum per cell; electronic readers can read figures if there is a link to an Excel spreadsheet with the data or if there is a short text description. With these principles and best practices, tables and figures will highlight the key findings of scientific studies in a way that is clear, accessible and memorable.

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Suggested citation: Huston P. Effective presentation of data in tables and figures. Can Commun Dis Rep 2020;46(7/8):242–6. https://doi.org/10.14745/ccdr.v46i78a05

Keywords: tables, figures, scientific publications, data presentation, best practices

Introduction

A hallmark of a scientific study is the presentation of data; yet authors often do not consider how they are going to present their data before starting to prepare manuscripts for publication. Definitive textbooks on this topic are available (1–4), as are articles in other disciplines (5–7). However, these sources generally do not consider international guidelines on ensuring that online publications are accessible to those visually impaired (8). These guidelines have been adopted by scientific publishers worldwide, and knowing how to comply with them prevents the need for subsequent revision.

The objective of this article is to provide researchers with a concise overview of principles and best practices for creating accessible tables and graphs in health research. Information on other types of figures, such as photographs, diagrams and biomedical images, can be found elsewhere (1).

Appropriate use

Tables and figures are often essential in communicating health research. To present data effectively, you need to apply two key principles and certain best practices. The two key principles are to highlight the main findings and to choose the appropriate format based on the type of data. Best practices include conventions for creating titles; structuring tables and figures; and making abbreviations and footnotes accessible so they can be read by those who use electronic readers with text-to-speech technology (9).

The question of how much data to include often arises when starting to prepare research findings for publication. The initial impulse may be to share all that has been gleaned. With the growing trend towards open science and open data, this is now in fact possible: whole datasets are being posted and made accessible online (10). In a scientific publication, however, a clear focus helps readers identify and retain the key findings of a study; too much data can be overwhelming. On the other hand, if readers are presented with too little data, they may get the impression that there is a lack of substance to support the scientific findings.

The best way to get the presentation of data in tables and figures just right is to use these to focus on the main findings, including both the results of the methodology (more on this below) and the main outcome measures of the study. Know that,

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as part of assessing whether a manuscript is appropriate for a journal, editors will assess if the information provided by the figures and tables is warranted based on the paper's length and if the manuscript fits within the journal's space limits (11). As a general rule of thumb, medical journal articles typically include three to four tables and figures and often no more than five to seven.

Methodes

There are at least three instances when a table or figure showing pertinent information on the methodology is indicated: randomized clinical trials, systematic reviews and studies that involve two or more populations. For randomized clinical trials, the CONSORT statement has identified the need for a flow diagram to show how many people were invited to join the study, how many accepted and were randomized, how many were in each group, and how many dropped out or completed the study (12).

In systematic reviews, the PRISMA statement has identified the need for a flow diagram to show the results of the literature search and the winnowing down of the studies based on inclusion and exclusion criteria (13).

In epidemiologic studies involving two or more groups (such as a nested case–control study), the STROBE statement notes the need to describe the demographic, clinical and social characteristics of study participants, and information on exposures and potential confounders for cases and controls (14); a table is the most efficient way to do this. A table also helps readers assess whether the groups were similar at the start of the study; randomization does not always result in equivalent groups. In both randomized controlled trials and case–control studies, if one group ends up with more co-morbidity, for example, this may bias the results and needs to be taken into account when interpreting the results.

Main outcomes

Key research findings include the main outcome measure and, often, a number of secondary measures that are all linked to the objective of the study. The objective can have several components. For example, if the objective of a study is to examine trends in new HIV cases over a certain period of time by age, sex, geographic location and risk group, each of these areas would be addressed in the results. One would anticipate data in each of these areas to be visually displayed.

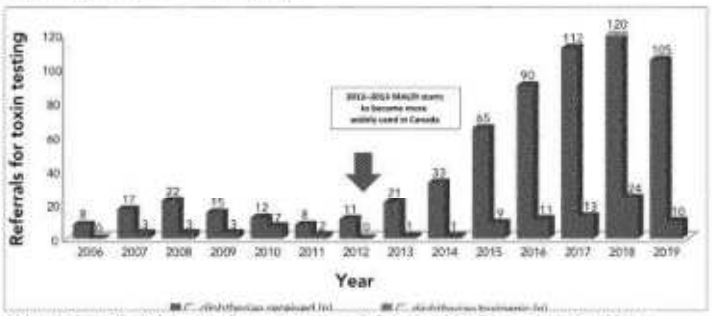
Once you have identified what you want to highlight, the question is "is it best to present the data in a table or a figure?". The answer depends on the type of data you have to present. A trend over time is best presented in a figure. If exact values are important, or there are many, these are best presented in a table (1).

Figures

Figures can provide instant information that would otherwise take many sentences to explain. A graph or a histogram easily and memorably shows comparative data or identifies trends over time. For example, a graph is commonly used in surveillance summaries and outbreak reports to show disease incidence.

For graphs, the y-axis identifies the measures of interest (such as rates or the number of cases) and typically begins at zero. The x-axis represents the independent variable, for example, time (by days, months or years) (see **Figure 1**). Such a visual display makes it instantly obvious whether rates are increasing, decreasing or staying about the same. If you need to condense the height of the graph, the y-axis can be a logarithmic scale or you can use a pair of diagonal lines (-- // --) to show that the scale is not continuous.

Figure 1: *Corynebacterium diphtheriae* referrals for toxin testing by year and subset by number of toxigenic strains, 2006–2019 (15)



Abbreviations: *C. diphtheriae*, *Corynebacterium diphtheriae*; MALDI, matrix-assisted laser desorption/ionization spectrometry
Source: Bernard *et al.* 2019 (15)

Colour can be used to differentiate between different lines in graphs or bars in histograms, but to meet accessibility guidelines, the colours need to be sufficiently different to pass a colorblind test or have an additional design feature to distinguish them. Figures need a legend to identify each line or bar. In Figure 1, the legend identifies the data represented by the red bars and the blue bars; both of these colours passed colorblindness testing.

Tables

Precise outcomes and multiple types of data are best presented in tables. When constructing tables it is useful to consider both structure and the placement of content.

Structure

Authors often wonder what data to note in rows and what data to note in columns. A general principle is dependent or outcome variables are identified in rows and independent variables are

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identified in columns (1). For example, if you are comparing the characteristics of two study populations, the study populations would be identified in columns and the different baseline characteristics or outcomes would be presented in rows. English and French is read horizontally and noting the characteristics in columns enables readers to more easily compare the two populations.

Each column needs a heading that describes what is in the column. Headings that span two or more columns are called spanner headings. For example, spanner headings might describe different populations (e.g. "Documented two-dose vaccination," "Documented one-dose vaccination" and "No documentation or no history of vaccination"). Under each spanner heading are two column headings for "n" and "%" (**Table 1**).

Table 1: Names and components of a scientific table[a]

Column heading for stub and row headings		Spanner head				Total	
		N	%	N	%	N	%
Stub heading	Row heading 1	-	-	-	-	-	-
	Row heading 2	-	-	-	-	-	-
	Row heading (n)	-	-	-	-	-	-
Stub heading	Row heading 1	-	-	-	-	-	-
	Row heading 2	-	-	-	-	-	-
	Row heading (n)	-	-	-	-	-	-
Total	-	-	-	-	-	-	100

Abbreviation: -, not applicable
[a] Adapted from Style Manual Subcommittee, 2014 (1)

The far left column heading describes what is in the rows. In the far left of each row are row headings. Stub headings, which organize row headings into groups, can be included. Each row heading describes the data in the cells to the right. Consider the order of the row headings. This may be in chronologic order (e.g. "status on admission," "status at discharge," "status six months post-discharge"); in alphabetical order (such as the names of different countries if you are comparing their incidence of diseases) or geographically (e.g. disease incidence in Canada by province or territory from west to east). Ensure that each spanner, column, stub and row heading accurately describes what is presented in the cells it covers.

Write only one datum per cell and leave no cell empty. The convention used to be to write the "n" value followed by the percentage in brackets in a single cell. As seen in Table 1, these are now written in separate columns in order to be accurately interpreted by electronic readers (8,9). If the datum is zero, write zero. If there are no data, write "ND" (for "no data") or "NA" (for "not applicable") and explain the abbreviation below the table.

Content

Usually numeric results in tables are right justified and numbers are aligned on the decimal point (1). If the total sample size is less than 100, use percentages as whole numbers (i.e. no decimal points) so you do not give the impression of greater precision than is merited (3). Likewise, if the total sample size is less than 20, no percentages need be reported (3). If the units vary in a column (for example, if you are reporting on different blood test results), the units need to be identified in the row headings and the data in each cell may be centred.

When indicated, add a column for a statistical measure of variation, such as standard deviation or standard error of the mean, and another column for the *p* value (11).

In general, the entire study sample should be accounted for (3). If you are missing data for some elements (for example, if a survey participant did not respond to some questions), consider adding a "no response" category so readers can consider how this may affect the overall results. Related to this is that both the actual number (or "n") and the percentage should be given and all the percentages should add up to 100% (3). To demonstrate this, there is often a total in the far right column and/or the bottom row.

Once the table is constructed there are a few finishing touches to consider, for example, how to minimize empty space. For text tables, use abbreviations and symbols to minimize column width, and then adjust column widths so the columns that contain the most information have the largest width. Finally, always double-check the numbers in the table with the original data and ensure any corrections are reflected in the text.

Best practices

There are a number of best practices that cover all the other information that may be associated with tables and figures. This summary is based on the definitive style manual for scientific publications, *Scientific Style and Format* (1), the international *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals* (15) and the *Web Content Accessibility Guidelines* (8).

Titles

The title of a table or figure should give enough information that it explains the data in the table without having to read the context in the article. Consider each table and figures as a "stand

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alone." The title should be concise but complete, and include who and what, when and where and, when indicated, the total sample size. A set of tables or figures containing similar types of information calls for a parallel format for the titles. For example:

- Figure 1: New HIV cases in Canada, 2019, by geographic area (n=)
- Figure 2: New HIV cases in Canada, 2019, by age and sex (n=)
- Figure 3: New HIV cases in Canada, 2019, by risk factor (n=)

Abbreviations, footnotes and references

Abbreviations are generally identified in the line immediately under a table or figure and are listed in alphabetical order (e.g. AST, aspartate aminotransferase; DWI, driving while intoxicated, etc.). Even if abbreviations have been introduced in the text, they should be redefined under a table or figure so that these can be stand alone.

Footnotes are used when more explanation is needed. Footnotes are identified by placing a letter in superscript (beginning with "a" and proceeding in alphabetical order) immediately following the words or numbers that need additional explanation. Numbers are eschewed for footnotes as electronic readers may confuse them with either results or reference numbers. Footnotes are identified sequentially in the same order as one reads – from left to right in rows and from top to bottom. As shown in Table 1, the footnotes are placed sequentially, below the abbreviation line.

References are identified in tables to either show the source of a table or support an assertion in a footnote. References cited only in tables or figure legends should be numbered based on where the table or figure is first cited in the text. For example, Figure 1 above has a reference after the title that keeps the citations in numeric order.

Additional data

If you use data from other published or unpublished sources that are not in the public domain, you need to submit to your publisher written permission from the copyright holder to reproduce these data (11). There is a trend now to move away from copyrighted articles to the public domain, such as with a Creative Commons licence (16). In any case, it is important to identify the source and indicate if any changes were made to the original.

Occasionally, additional tables containing backup data may be appropriate in an appendix or a supplement or they are made available to readers directly by the authors upon request. This is something that is negotiated with the journal editor. When agreed to, a statement is added to the text to inform readers that this additional information is available and where it is located. Additional data are typically included with the manuscript upon submission so that the data are available as part of the peer review process.

Identification in text

Each table and figure in an article should be identified in the text. Tables and figures are numbered in order and the publishing convention is to place them at the end of the paragraph where they are first identified. However, for manuscript submission, most medical journals request that authors place the tables and figures at the end of the manuscript (11). This allows editors and reviewers to focus on the text and the data presentation separately. Tables and figures are placed in the text during layout based on convention, but this may be altered slightly to maintain a pleasing layout to the article. It is useful to know this and avoid making statements like: "See Tables 1–4" as this means the text would normally be followed by four tables, which breaks up the flow of the text and creates formatting challenges on the printed page.

Accessibility

Electronic readers are able to read tables – as long as there is only one datum in each cell – but they are not able to read figures. To accommodate this, either include an Excel spreadsheet (for graphs, histograms and pie charts) or add a text description (for flow diagrams and illustrations). **Table 2** shows an Excel-type table used to identify the data in Figure 1. In the HTLM version of the original publication, the table was hyperlinked to the word "Text Description" found below the figure (15).

Conclusion

Creating effective tables and figures is essential to successfully communicate scientific research. When developed to highlight the main findings of a study and constructed based on best practices, tables and figures help to make the results of a scientific study clear, accessible and memorable.

Table 2: Text description of Figure 1 for people with visually impaired

Species	Toxigenic strains/year														
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
C. ulcerans received (n)	0	3	1	0	0	0	0	4	5	1	0	1	2	5	22
C. ulcerans toxigenic (n)	0	1	1	0	0	0	0	1	4	0	0	0	1	2	10

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Author's statement

PH conceived and wrote the article.

Conflict of interest

None.

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Considerations for mandatory childhood immunization programs

Noni E MacDonald[1]*, Eve Dubé[2], Daniel Grandt[3]

Abstract

Outbreaks of vaccine preventable diseases occur even in countries that have unrestricted and relatively equitable accesses to immunizations because vaccine uptake rates are lower than necessary for effective disease control. Vaccine hesitancy is seen in many countries, including Canada, and has led to enacting or strengthening legislation requiring mandatory childhood immunization in some provinces. Although mandatory immunization may seem to be the simplest solution to this issue, it is not always as effective as anticipated. Different countries/states/provinces/territories have used different strategies to encourage parents to fully immunize their children. Definition, scope, flexibility (such as exemptions for medical, religious and philosophical reasons) and framework factors (such as strictness of application and levels of enforcement of the mandate) vary widely between jurisdictions. Surprisingly, no marked differences were seen in vaccination rates between countries that recommended versus mandated them. Unintended consequences of mandatory immunization programs—both good (increased availability of data) and bad ("gaming" of the system and disproportionate impacts on families of lower socioeconomic status) have been reported. Addressing lower vaccine uptake rates is a complex problem that needs a multipronged, more nuanced and tailored approach.

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Suggested citation: MacDonald NE, Dubé E, Grandt D. Considerations for mandatory childhood immunization programs. Can Commun Dis Rep 2020;46(7/8):247–51. https://doi.org/10.14745/ccdr.v46i78a06
Keywords: childhood immunization, mandatory, CANVax

Introduction

Outbreaks of vaccine preventable diseases occur even in high-income countries that have unrestricted and equitable access to immunizations. The reason for these outbreaks is that vaccine uptake rates are not where they need to be for adequate control of vaccine preventable diseases. Parents in many jurisdictions, including Canada, have been hesitant about immunizing their infants and children on time and on schedule (1). As a consequence, several countries have discussed, enacted or strengthened mandatory childhood immunization legislation to address this vaccine hesitancy problem (2–4). Mandatory immunization is seen as a "simple" solution to the problem. Historically, three factors appear to act as triggers for the implementation of mandatory childhood immunizations: failure of incentives to achieve desired vaccine uptake rates; response to a vaccine preventable disease outbreak that is difficult to control because of lower than desired vaccine uptake rates; and the push to achieve a vaccine preventable disease elimination goal, such as for polio (5).

Given that queries have also been raised in the press about whether coronavirus disease 2019 (COVID-19) vaccine(s), when available, should be made mandatory for some or all in Canada, this Canadian Vaccination Evidence Resource and Exchange Centre (CANVax) Brief provides an overview and brief discussion of what mandatory childhood vaccination means followed by discussions of scope and framework factors to consider. Also discussed are the reported outcomes, including reports of unintended consequences.

This is the sixth in a series of articles, produced by CANVax, an online database supporting immunization program planning and delivery. This series includes both the identification of existing resources and the description of the new resources developed by a multidisciplinary group of professionals (6). The article is one of a series and shows how the various aspects of vaccine hesitancy that have been considered to date can be applied to fostering vaccine acceptance.

Definition, scope and frameworks of mandatory immunization programs

In 2010, an expert group proposed the definition that a "mandatory" vaccine is one that every child in the country/state/

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province/territory must receive by law without the option for the parent to accept or refuse it, independent of whether a legal or economical implication or sanction exists for the refusal (7). Mandatory immunization programs vary widely. There is neither a uniform approach for establishing mandatory immunization programs nor a common scope for such programs. Hence, it is critical when discussing any mandatory program for childhood vaccinations (and/or for other age groups) to understand what that program entailed and what it was hoped that program would achieve.

With respect to childhood immunizations, the scope of the mandate may apply to the entire country (Italy (3) and France (3)) or to specific constituent states, territories or provinces (California, United States (US) (3) and Ontario, Canada (8)), or it may apply more narrowly to a defined subset of the child population (9). Some programs cover most but not all of the World Health Organization (WHO) recommended childhood vaccines (e.g. Italy (3)), another may identify a limited range of vaccines (e.g. France, a specific list (3)) and another only one vaccine (Belgium, polio vaccine (10)). Some may specify an age group or milestone such as on school entry (Italy on enrolment in kindergarten) (3) and California, US, on school entry). With respect to flexibilities, some contain exemptions for medical contraindications only, while others include or previously included exemptions for religious and philosophical reasons (California, US (4) and Australia (11) prior to 2016).

Framework factors, such as strictness of application and levels of enforcement of the mandate, also vary, as can the body responsible for enforcement of the mandatory requirements (California, US) (4). Other programs may not enforce the mandate at all (Serbia). The program may focus on financial incentives to encourage compliance (11) or impose penalties that maybe financial or social (e.g. children can be precluded from daycare (Ontario, Canada (12) and Australia (11)) or school entry (California, US). Individuals may be precluded from access to theme parks (California, (12)) or they may be fined (Slovenia (10)) or even imprisoned (Uganda (13)).

There is a wide diversity of approaches to mandatory childhood immunization required by law:

- No enforcement, anyone can opt out without penalty (e.g. France before changes in 2018 (2))
- Opt out due to personal or philosophical objection without penalty (e.g. Ontario before changes in 2016 (14))
- Laws requiring parental education about immunization (rather than immunization itself); opt out with personal or philosophical objection but requires specific forms and notarization but no penalty for noncompliance (e.g. Ontario (8))
- Laws requiring immunization but opt out with personal or philosophical objection that requires specific forms and added effort. There is a penalty for noncompliance and strict enforcement (e.g. Australia before changes in 2016 (11))
- Laws requiring immunization with serious financial penalties or social restrictions; only allowing medical exemptions; strict enforcement (e.g. California, US after 2016 (4,15) and Australia after 2016 (11))

Outcomes of mandatory immunization programs

There are surprisingly few systematic reviews, and very little comparative evidence on the outcomes of mandatory infant and childhood immunization programs. A 2006 report noted no strong difference in vaccination rates between countries that only recommend certain vaccinations and countries that mandate them (16). A 2016 systematic review of outcomes of mandates found only 11 before and after studies, and 10 studies comparing immunization rates in similar populations with and without mandates. Overall, the authors concluded that mandatory immunization was generally helpful to increase vaccine uptake rates, albeit 18 of the included studies originated from one country, the US, with only two from Canada and one from France (17). This review did not assess the impact of mandatory immunization on attitudes toward immunization.

In 2018, a landscape review of the legislative environment for childhood immunization was conducted in 53 countries of the European region (18). Findings of this review showed a diversity of legislative frameworks for immunization (from recommendations to strong mandatory policies) with no clear evidence for the "best approach" to enhance vaccine uptake and acceptance (i.e. uptake rates did not correlate with presence or absence or type of legislation). To interpret the results correctly it is necessary to understand the differences that exist between mandatory immunization programs in a historical and geographical context. The 15 ethnic Republics that composed the former United Soviet Socialists Republic and its communist neighbours all had very strong centralized public health systems with mandatory vaccination that enabled enforcement without question and was associated with high uptake rates. By 2018, however, much had changed with respect to childhood immunization in many of these countries. By 2018, Ukraine had the lowest childhood vaccine uptake rate in the WHO European Region, and Serbia and Poland had experienced protests against mandatory immunizations.

There have not been studies of mandates in high-income countries in jurisdictions with relatively high baseline rates or with mandates for child-care centers. In Belgium and Italy, for example, some vaccines were mandatory for historical reasons and others were not. Non-mandatory vaccines may have been perceived by the public and health care professionals as being less important and less necessary. In Italy, this divergence in the program led to high coverage (all greater than 93%) of the mandatory vaccines (e.g. diphtheria, tetanus, poliomyelitis and hepatitis B) but lower than needed coverage of other

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recommended but not mandated vaccines (e.g. measles coverage was 87%) (3). Measles outbreaks led Italy to move to broader mandatory immunization (3).

In Australia, in 2015, due to concerns about uptake rates, the *No Jab No Pay* amendment bill removed the vaccination "conscientious objection" exemption to vaccination requirements (11). By March 2017, these changes were associated with an increase in vaccine uptake among five-year olds from 92.59% to 94.34% (10) but, as noted below, the impact of the change was not uniform across socioeconomic classes.

In Ontario, tightening of the mandatory process required to obtain a philosophical exemption has revealed valuable information, as this newly available record-level data has permitted more detailed analysis (19). In 2016–2017, 2.4% of students had a non-medical exemption to at least one antigen; however, there were also students who were not yet immunized but who had not requested an exemption. Furthermore, having a signed non-medical exemption did not always correlate with non-immunization. The likelihood of having a non-medical exemption and not being immunized was higher for private or other non-government funded schools and specific geographic areas. In addition, older and/or disadvantaged students were less likely to have a non-medical exemption.

Unintended consequences of mandatory immunization programs

Mandatory immunization programs have the potential for unintended consequences. The removal of non-medical exemptions (i.e. personal belief exemptions) has led to an increase in medical exemptions in California, US (20) and Australia (11). Regions with high previous rates of personal exemptions before the instigation of more restrictive laws appear to develop higher rates of medical exemptions. This suggests a "gaming" of the system. Disappointingly, the target population response has been to seek medical exemption rather than to accept immunization.

In Australia, the *No Jab No Pay* mandatory childhood immunization program did increase immunizations as noted above; but disproportionately children and families living in poverty were most negatively affected, leading to equity and justice concerns (11).

An unintended benefit of mandatory programs is the requirement for greater attention to data collection on who is immunized. This was notable in Ontario where time, attention and funds were paid to make the childhood immunization registry functional.

COVID-19 vaccines and consideration for a mandatory approach

While a poll in Canada in late April 2020 reported strong support amongst the general public for making COVID-19 vaccination mandatory (21), this strategy can only be considered when these vaccines become widely available in Canada. Given that a mandatory program has costs both in terms of implementation and monitoring (5), decisions need to rest on what additional benefit is hoped to be achieved. If vaccine uptake is already expected to be high amongst groups deemed necessary for the control of the spread of COVID-19, then the added costs of a mandatory program are likely not justified. In contrast, if the rates of uptake are low and the ease of access and other strategies known to improve uptake have been addressed, then a mandatory approach may be worth pursuing. Careful attention must be paid to whether this will be an incentive or penalty program, how it will be monitored and by whom (5).

Conclusion

There is no standard global approach to mandatory immunizations. Which vaccines are included, which age groups are covered, program flexibility and rigidity (e.g. opportunities for opting out, penalties or incentives and degree of enforcement) all have to be considered. Mandatory immunization for childhood vaccines is no guarantor that the problem of lower-than-desired vaccine uptake rates will be overcome, although it can lead to increased uptake. There were no strong differences in vaccination rates between countries that only recommend certain vaccinations and countries that mandate them. Context matters; different countries have implemented or not implemented mandatory immunization for different reasons, different circumstances and used different approaches. Furthermore, unintended consequences like a reduced acceptance rate of non-mandatory immunizations needs to be anticipated as well as the possibility of vaccine-hesitant individuals gaming the system. Rigid mandatory vaccination requirements may appear, at the first sight, to be the simple solution to improving vaccine uptake rates; however, evidence does not strongly support this conclusion. Mandatory immunization is but one strategy to consider. Addressing lower vaccine uptake rates is a complex problem that needs a multipronged, more nuanced and tailored approach (22).

Authors' statement

NEM — Writing original draft
ED — Writing, review & editing
DG — Writing, review & editing

Competing interests

Dr. MacDonald reports grants from the Public Health Agency of Canada, the Canadian Institutes of Health Research, Nova Scotia Health Authority, IWK Health Authority and the Canadian

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Immunization Research Network. Dr. Dubé reports grants from the Public Health Agency of Canada, the Quebec Ministry of Health and Social Services, le Fonds de la recherche en Santé du Québec, the Canadian Institutes of Health Research, the Canadian Immunization Research Network, and the Social Sciences and Humanities Research Council of Canada.

Acknowledgements

Contributions to CANVax come from a very wide range of authors, committees, immunization partners, reviewers and especially the CANVax secretariat at Canadian Public Health Association.

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CANVax

CANVax is the first online resource of its kind in Canada to equip public health professionals with access to a centralized resource centre focused on vaccine acceptance and uptake.

https://www.canvax.ca/

ALREADY PUBLISHED IN CCDR

A new resource to summarize evidence on immunization from the Canadian Vaccination Evidence Resource and Exchange Centre (CANVax) – CCDR Vol. 46 No. 1 (January 2, 2020)

Promoting immunization resiliency in the digital information age – CCDR Vol. 46 No. 1 (January 2, 2020)

Optimizing communication material to address vaccine hesitancy – CCDR Vol. 46 No. 2/3 (February 6, 2020)

Motivational interviewing: A powerful tool to address vaccine hesitancy – CCDR Vol. 46 No. 4 (April 2, 2020)

Vaccine acceptance: How to build and maintain trust in immunization – CCDR Vol. 46 No. 5 (May 7, 2020)

Managing immunization stress-related response: A contributor to sustaining trust in vaccines – CCDR Vol. 46 No. 6 (June 4, 2020)

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Infectious disease climate change fund

Source: Public Health Agency of Canada. Infectious Disease and Climate Change Fund; PHAC. Ottawa (ON) 2020. https://www.canada.ca/en/public-health/services/funding-opportunities/infectious-diseases-climate-change-fund.html

Public health plays an important role in raising awareness about the effects of climate change by equipping health professionals, and decision-makers at various levels of government with tools and information to help Canadians to prepare and be more resilient to the impacts. The public health role in addressing climate change requires new partnerships, collaborations through multijurisdictional and multidisciplinary actions (https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2018-44/issue-10-october-4-2018/article-6-lyme-disease-grants-contributions-2018.html). The following projects funded by the Public Health Agency of Canada's Infectious Disease and Climate Change Fund (https://www.canada.ca/en/public-health/services/funding-opportunities/infectious-diseases-climate-change-fund.html) are just a few that are helping to advance knowledge and increase capacity within Canada to address climate-driven infectious diseases, such as Lyme disease.

eTick (Bishop's University)

This innovative project, bringing science into the hands of Canadians, is a bilingual public platform for image-based identification and population monitoring of ticks in Canada. By submitting a tick picture on eTick.ca or through the new eTick mobile app, you can get a species identification by trained personnel within 1 business day, to know if you or your pet might have potentially been exposed to tick-borne diseases, such as Lyme disease. Once the tick has been identified, your submission will automatically appear as a dot on an interactive distribution map and awareness/education materials. They have recently expanded the eTick (http://etick.ca/) website and launched a new eTick app [available in English and French for iOS (https://apps.apple.com/ca/app/etick/id1501804954?l=fr) and Android (https://play.google.com/store/apps/details?id=com.comit.etick)].

While the website and app are currently available to residents of Newfoundland and Labrador, Nova Scotia, New Brunswick, Québec, Ontario and Saskatchewan, Bishop's University is working to expand its partnership with other Canadian jurisdictions.

Climate-driven vector-borne disease guidelines (Canadian Association of Schools of Nursing)

The Canadian Association of Schools of Nursing have recently released Guidelines for Undergraduate Nursing Education on Climate-Driven Vector-Borne Diseases [available in English and French (https://www.casn.ca/2020/04/guidelines-for-undergraduate-nursing-education-on-climate-driven-vector-borne-diseases/)]. These are national, consensus-based guidelines that offer direction to nursing faculty on curriculum development on climate change and vector-borne diseases (VBDs). The domains and accompanying entry-to-practice learning outcomes in this guideline delineate the key knowledge, skills, and attitudes that all new registered nursing graduates in Canada should possess to support and care for individuals, families, communities, and populations affected by, or at risk of being affected by, climate-driven VBDs.

Early Lyme disease Management in Primary Care (Centre for Effective Practice)

Already the most common tick-borne illness in Canada, the incidence of Lyme disease is increasing due to blacklegged tick population growth (https://www.canada.ca/en/public-health/services/funding-opportunities/infectious-diseases-climate-change-fund.html). Improved diagnosis and treatment of early localized Lyme disease will help keep patients from progressing into later-stage disease. The Centre for Effective Practice has developed a new clinical tool on Early Lyme Disease Management in Primary Care (https://cep.health/clinical-products/early-lyme-disease/) to help health care providers diagnose and treat early localized Lyme disease. A complementary patient resource has also been developed to provide information for patients who have been bitten by a tick or diagnosed with early Lyme disease.

Prairie Climate Centre *(University of Winnipeg)*

The Prairie Climate Centre is uniquely focussed on translating scientific knowledge for diverse audiences on the Climate Atlas of Canada (https://climateatlas.ca). They proficiently combine sophisticated climate science with visualization tools, compelling narratives, and engaging video content to educate and inform the public about climate change. The Prairie Climate Centre's initial PHAC-funded work has focused on Lyme disease, in which they interviewed experts across the country and created a video, article, and map to serve as Lyme disease and climate change risk communication tools for the general public, frontline health workers, researchers and scientists. These tools were then tested with communities across urban and rural southern Manitoba, and feedback was integrated to further increase their efficacy for diverse audiences. The final tools can be found on the "Lyme Disease Under Climate Change" (https://climateatlas.ca/lyme-disease-under-climate-change) page of the Climate Atlas.

This work is part of a broader initiative called *Stories of Health and Hope* that will bring together science and storytelling regarding climate change, infectious disease, and how these issues combine to affect public health. Through workshops, interviews, and dialogue this project documents diverse health impacts and adaptations across various sectors/scales and synthesize findings using multi-media approaches and best practices in climate and health communications. These outcomes will be continue to be shared on the Health Topic Page (https://climateatlas.ca/topic/health) on Climate Atlas of Canada.

To learn more about the Infectious Disease and Climate Change Fund, the current funded projects and for future solicitation opportunities please visit this link (https://www.canada.ca/en/public-health/services/funding-opportunities/infectious-diseases-climate-change-fund.html).

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Beware the public opinion survey's contribution to misinformation and disinformation in the COVID-19 Pandemic

Source: Macdonald NE, Dubé E, Greyson D, Graham JE. Beware the public opinion survey's contribution to misinformation and disinformation in the COVID-19 Pandemic. https://canvax.ca/brief/beware-public-opinion-surveys-contribution-misinformation-and-disinformation-covid-19

The COVID-19 pandemic has been accompanied by an "infodemic" of misinformation and disinformation. Given the large degree of uncertainty, the complexity of the science, and rapidly evolving knowledge, well-intentioned misinformation is not surprising. As scientists race to understand a new disease, partial information and guesswork fill the gap until reliable research evidence is established. Unfortunately, disinformation, defined as deliberately false or misleading information, can be expected when crises are used as opportunities to make money or to undermine existing institutions, including education and health care systems. Regardless of intention, misleading information can spread rapidly in the era of social media and 24/7 news coverage, aided by the influence of fear, anxiety, and stress on learning, beliefs, and health decisions. It is therefore incumbent on those conducting COVID-19 rapid research, especially research associated with public awareness and knowledge translation, to avoid contributing to the spread of misinformation and disinformation through their work.

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COMING THIS FALL 2020!

THE WEBINAR

National Collaborating Centre for Infectious Diseases

Centre de collaboration nationale des maladies infectieuses

INFECTIOUS DISEASE EXPERTS
will present this **season's flu recommendations**, followed by an **interactive Q&A**.

Dr. Ian Gemmill

Dr. Robyn Harrison

Dr. Gerald Evans

Learn about the **2020-2021**:
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- The use of antivirals
- Infection and prevention control measures to reduce the risk of COVID-19 transmission at the time of flu vaccine administration.

To receive notification of webinar details and registration links, when they become available, please subscribe to NCCID News Alerts:

https://centreinfection.formstack.com/forms/alerts

This webinar will be in English. A French transcript will be available on NCCID's website after the event.

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https://www.canada.ca/ccdr

Également disponible en français sous le titre :
Relevé des maladies transmissibles au Canada

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From: Macey, Jeannette (PHAC/ASPC)
Sent: 2021-01-07 7:42 PM
To: Tam, Dr Theresa (PHAC/ASPC); Njoo, Howard (PHAC/ASPC)
Cc: Ponic, Pamela (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Leung, Teresa (PHAC/ASPC); Clark, Julia (PHAC/ASPC); Archibald, Chris (PHAC/ASPC)
Subject: Abridged Weekly Vaccine Coverage and Vaccine Safety Reports
Attachments: JMversion Vaccine Coverage_Vaccine Safety Reports_Internal Daily AEFIs Jan7.docx; Weekly Report on COVID-19 Vaccination - stripped.docx; 2020-01-08 COVID-19 Vaccine Safety Weekly Report_FINAL_for posting.docx

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Hi TT/HN – For reference – here is my cheat sheet/abridged version of the Vaccine Coverage and Vaccine Safety Webpages that will go live tomorrow [11:45am if all goes to plan] and on the second page today's internal daily report of AEFIs. As I noted in my previous email, the internal daily AEFIs with data as of January 7 is at 13 AEFIs, whereas the web report which includes data up to Jan 1st is at 9 AEFIs.

If you want to see what the web versions of the report look like, just click on the highlighted Dev links in my "abridged" version pasted below (also attached). In a bit messier format, CIRID colleagues have provided the final data (raw data, tables etc.) for the webpages in the second and third attachments above.

For your info on AEFIs versus doses administered:

- As of January 1st, 115,072 vaccines have been administered and 9 AEFIs have been reported (0.008%)

Jeannette

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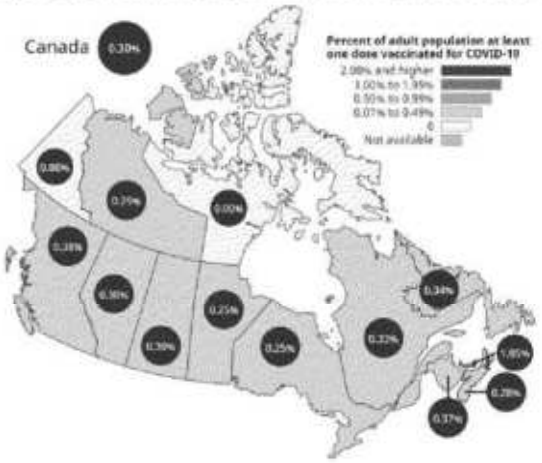
BACKGROUND/reference ...Abridged version of new Canada

COVID-19 Vaccination Coverage report - DRAFT, as of January 2, 2021

[Dev Link: https://infobase-dev.com/covid/vaccination-coverage/index-en.html**]**

- **424,050 doses delivered** to provinces and territories as of



January 4, 2021

- **0.30% of the population* received one dose** of COVID-19 vaccines (0% rec'd 2 doses), including:
  - 7.8% of Healthcare workers
  - 0.5% of adults aged 80 years and older
  - 2.2% of adults in group living settings for seniors

Coverage by vaccine product:

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- 1.29% of people in Canada have received one dose of the **Pfizer-BioNTech** COVID-19 vaccine, while 0.00% have received two.
- 0.05% of people in Canada have received one dose of the **Moderna** COVID-19 vaccine, while 0.00% have received two.

* Data from Ontario are not included in this value as only information on the total number of people vaccinated was available at the time of report.

Vaccination coverage information on adults in remote and isolated Indigenous and northern communities will be included in future weekly reports when data become available.

COVID-19 Vaccine Safety report – DRAFT, data up to and including January 1, 2021
[Dev Link: https://infobase-dev.com/Benoit/vaccine-safety/index-en.html**]**

- **No safety signals identified,** i.e. AEFIs reported to date considered within the range of expected adverse events
- **115,072** doses administered (9 AEFI/115072 = 0.008%)
- **9 AEFIs:** including 5 serious (with limited information, investigation continuing) and 4 non-serious events
  - All among adults aged 18 to < 50 years old, where age was known
  - All in females, where sex was known

- **In the 9 AEFI reports, there were 65 events reported.**
  - **of 8 adverse events identified in the serious reports:**
    - 2 Anaphylaxis
    - 1 Headache
    - 1 Severe allergic reaction
    - 1 Facial paralysis
    - 1 Chills
    - 1 Syncope
    - 1 Pain in extremity
  - **Most frequently reported non-serious adverse events** were Vaccination site reactions, Nausea, Paraesthesia, Pruritis, Urticaria
  - No deaths were reported.

Notes: one AEFI report (one person) may contain more than one adverse event. That is, one person may have experienced more than one adverse event following immunization. Although there is a possibility an AEFI report (one person) could be reported in both CV and CAEFFISs, the risk of duplicate reporting should be low, given that CV captures reports from manufacturers. Reconciliation between CV and CAEFISS happens on a weekly basis, which enables the detection and removal of duplicates before the weekly report is published on Fridays.

INTERNAL PHAC AEFI report for January 7, 2021

Summary:

Canada, 13 (0 fatal) AEFIs reported to date; 1 new
• 1 new Canadian AEFI* reported to CVD (no new reported to CAEFISS) as of Jan 7, 2021
  - non-serious, jurisdiction not specified
• To date, 13 reports have been submitted to the Health Portfolio
  - 3 BC; 3 SK; 2 ON; 2 NS; 3 no location specified Canada Vigilance Reports
• No fatalities reported

International, 867 (14 fatal) AEFIs reported to date; 181 new, including one fatal outcome
- none identified as causally associated to vaccine
- Age range from 20 to 90 years of age

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- 1 fatal case: 84 year old female with reported AE: Death (US); Cause of death reported: Unknown
- 5 cases of anaphylactic reactions (1 Germany, 1 UK, 3 UK)
- 5 cases of drug hypersensitivity reactions (1 Israel, 1 Portugal, 1 UK, 2 US)
- 1 case of syncope (UK)
- 2 cases of myocardial infarction (US)
- 1 case of seizure and facial paralysis (Germany)
- 12 cases of facial paralysis (3 Israel, 1 UK, 8 US)

No safety signals identified, meaning AEFIs reported to date are considered within the range of expected adverse events.

Note re: possibility of double counting in CV/CAEFISS: Although there is a possibility that an AEFI could be reported in both CV and CAEFFISs, in theory, the risk of this should be low, given that CV captures reports from manufacturers. There is a reconciliation between CV and CAEFISS that happens on a weekly basis, which enables the detection and removal of duplicates before the weekly report is published on Fridays. So there is a reasonable level of confidence that each reported AEFI represents a separate event and not duplicate reporting.

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This page provides information about any adverse events following immunization that individuals have experienced after receiving a COVID-19 vaccine in Canada. These adverse events are not necessarily related to the vaccine. We update this page every Friday at 4:00PM Eastern Time.

On this page

- What you need to know
- Definitions
- Summary of AEFI reports
- AEFI reports by vaccine type
- AEFI reports by age and sex
- Serious and non-serious adverse events reported
- Data notes
- Related links

What you need to know (up to and including January 1, 2021)

	No safety signals (potential safety issues) have been identified
Total of doses administered	115,072
Total adverse events following immunization reports	9
Adverse events following immunization reports were non-serious	4 of 9
Adverse events following immunization reports were serious	5 of 9

- The benefits of vaccines authorized in Canada continue to outweigh the risks.
- Health Canada, the Public Health Agency of Canada (PHAC), the provinces and territories, and manufacturers continue to closely monitor the safety of COVID-19 vaccines. We'll respond to any safety issues right away and will inform Canadians about any risks that arise in Canada.
- Of the 9 AEFI reports, 5 were considered serious with limited information and will continue to be investigated.
- All AEFIs were reported among the 18 to <50 year age group where age was known.
- All AEFIs were reported among females where sex was known.

Definitions

Adverse Event Following Immunization (AEFI)

An AEFI is any untoward medical occurrence which follows immunization. It isn't necessarily causally related to the usage of the vaccine. The adverse event may be any:

- unfavourable or unintended sign (for example: skin rash)
- abnormal laboratory finding
- symptom or

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- disease

For more information, please refer to the Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO). Definition and Application of Terms for Vaccine Pharmacovigilance. Report of CIOMS/WHO Working group on Vaccine Pharmacovigilance. Geneva: CIOMS and WHO; 2012.

AEFI report

Please note that one AEFI report (one person) may contain more than one advserse event. That is, one person may have experienced more than one AEFI.

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Serious AEFI

An event is considered serious if it:

- results in death
- is life-threatening (an event/reaction in which the patient was at real, rather than hypothetical, risk of death at the time of the event/reaction)
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity, or
- results in a congenital anomaly/birth defect

Medically important event

An event which may not be immediately life-threatening but requires intervention to prevent one of the outcomes listed above and may also be considered as serious. This is based on the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. See: International Council on Harmonisation (ICH). Support Documentation. Medical Dictionary for Regulatory Activities. https://www.meddra.org/how-to-use/support-documentation

Adverse Event of Special Interest (AESI):

This is a pre-specified medically significant event that has the potential to be causally associated with a vaccine product. It must be carefully monitored and confirmed by further special studies.
For more details, refer to: World Health Organization. COVID-19 Vaccines: Safety Surveillance Manual.

Safety signal

Information indicating a new and potentially causal association between a vaccine and an event that could affect health. The event is either unknown or incompletely documented. It could also indicate a new aspect of a known association. The primary purpose of vaccine post-market surveillance is to detect safety concerns. These concerns include a possible increase in the severity or frequency of expected AEFIs, or one or more unexpected events (i.e., an event that is not consistent with Canadian product information or labelling).
For more information, please refer to World Health Organization: Investigation of safety signals.

Summary of AEFI reports

The information in this report reflects detailed case information data from the Public Health Agency of Canada's Canadian Adverse Events Following Immunization Surveillance System and Health Canada's Canada Vigilance program. The data may undergo changes as more information about cases becomes available.

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There have been a total of 9 AEFI reports up to and including January 1, 2021 including 5 considered serious. The weekly and cumulative (coming next week) numbers of AEFI reports are shown in figure 1.

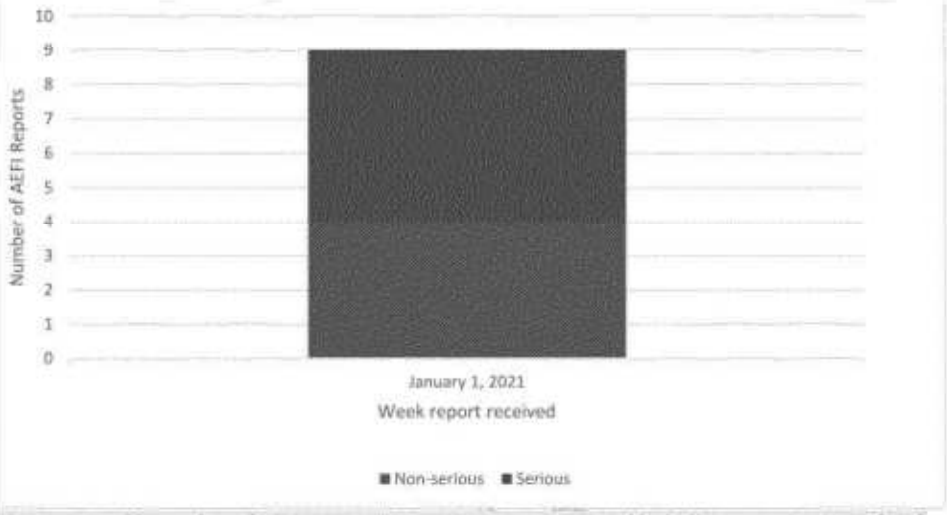

Figure 1: Weekly number of COVID-19 vaccine AEFI reports up to and including January 1, 2021 (n=9)

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Figure 1 text description

Weekly number of COVID-19 vaccine AEFI reports up to and including January 1, 2021 (n=9)

Week report received	Non-serious AEFI reports	Serious AEFI reports
January 1, 2021	4	5

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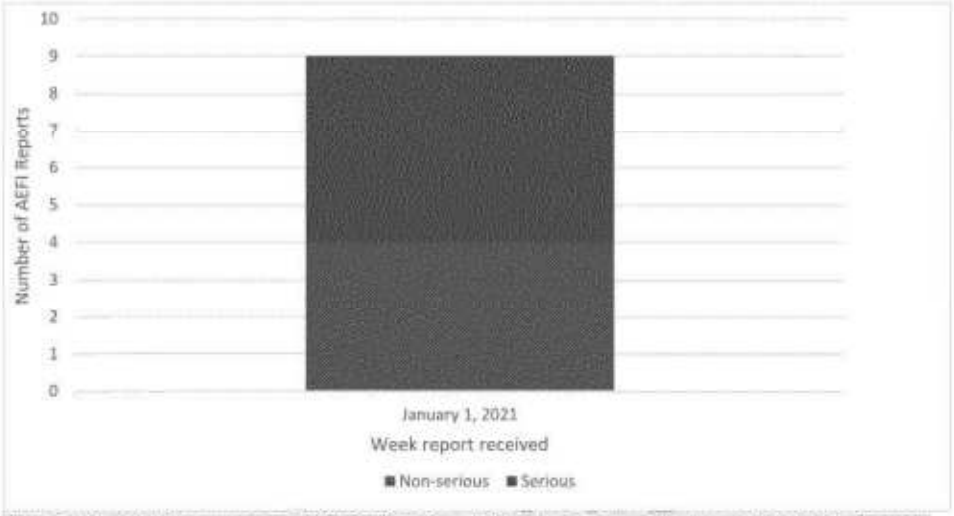

Figure 1: Cumulative number of COVID-19 vaccine AEFI reports per week up to and including January 1, 2021 (n=9)

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Figure 1 text description

Cumulative number of COVID-19 vaccine AEFI reports per week up to and including January 1, 2021 (n=9)

Week report received	Non-serious AEFI reports	Serious AEFI reports
January 1, 2020	4	5

AEFI reports by vaccine type

To date, AEFI reports have only been received for the Pfizer-BioNTech COVID-19 Vaccine, which was the first to be authorized in Canada.

AEFI reports by age and sex

People aged 18 to <50 years experienced the most AEFIs (Figure 2). All of the AEFI reports involved females (Figure 2) up to and including January 1, 2021.

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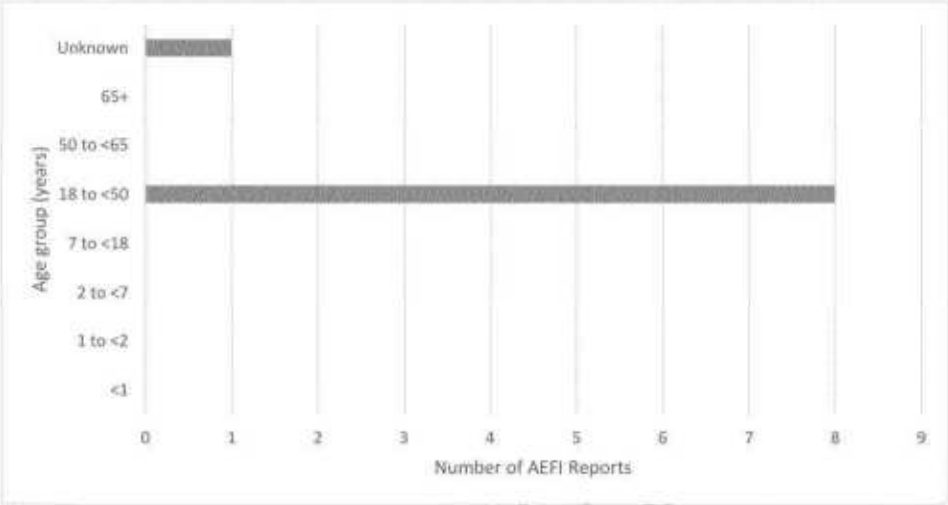

Figure 3: AEFI reports by age group up to and including January 1, 2021 (n=9)

Figure 3 text description

AEFI reports by age group up to and including January 1, 2021 (n=9)

Age group	Number of AEFIs
<1	0
1 to <2	0
2 to <7	0
7 to <18	0
18 to <50	8
50 to <65	0
65+	0
Unknown	1

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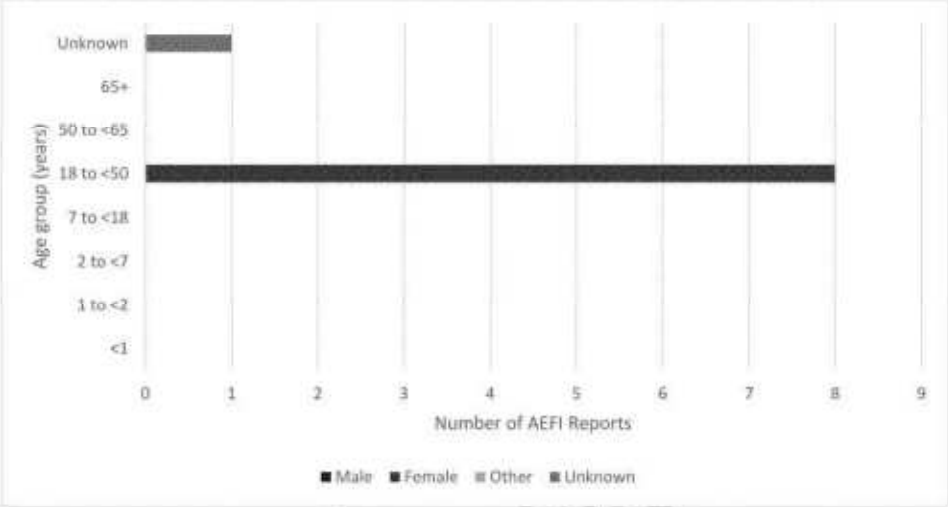

Figure 3: AEFI reports by age group and sex up to and including January 1, 2021 (n=9)

Figure 3 text description

AEFI reports by age group and sex up to and including January 1, 2021 (n=9)

Age group	Male	Female	Other	Unknown
<1	0	0	0	0
1 to <2	0	0	0	0
2 to <7	0	0	0	0
7 to <18	0	0	0	0
18 to <50	0	8	0	0
50 to <65	0	0	0	0
65+	0	0	0	0
Unknown	0	0	0	1

Serious and non-serious adverse events reported

- In the 9 AEFI reports, there were 65 adverse events reported.
- There were 8 adverse events identified in the serious reports, as follows:
  - Two anaphylaxis
  - One severe allergic reaction
  - One facial paralysis
  - One chills
  - One syncope
  - One pain in extremity
  - One headache

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- The most frequently reported non-serious advserse events were vaccination site reactions, nausea, paraesthesia, pruritis, and urticaria.
- No deaths were reported.

Data notes

The data presented in this report are estimates and may not accurately represent national COVID-19 vaccine AEFIs for the following reasons:

1. There may be delays in receiving reporting forms. These delays may be due to jurisdictions investigating and reviewing each AEFI prior to submitting the information to PHAC. There are also limitations to reporting practices such as underreporting, missing information, and differing AEFI reporting practices accross jurisdictions in Canada.
2. Information is collected on individuals for whom an AEFI report was submitted, not on the total number of individuals who experience an adverse event as not every adverse event is reported.
3. New information contained in this report is not comprehensive but rather represents preliminary results of data received on a weekly basis.
4. Note that reporting jurisdictions may refer to gender as opposed to sex.

Related links

- Canadian Adverse Events Following Immunization and Surveillance System (CAEFISS)
- Immunization Monitoring Program ACTive (IMPACT)
- Canadian National Vaccine Safety Network (CANVAS)
- Canada Vigilance Program
- Drug Product Database
- Approved COVID-19 Vaccine list
- COVID-19 vaccines and treatments portal
- COVID-19 vaccination coverage in Canada

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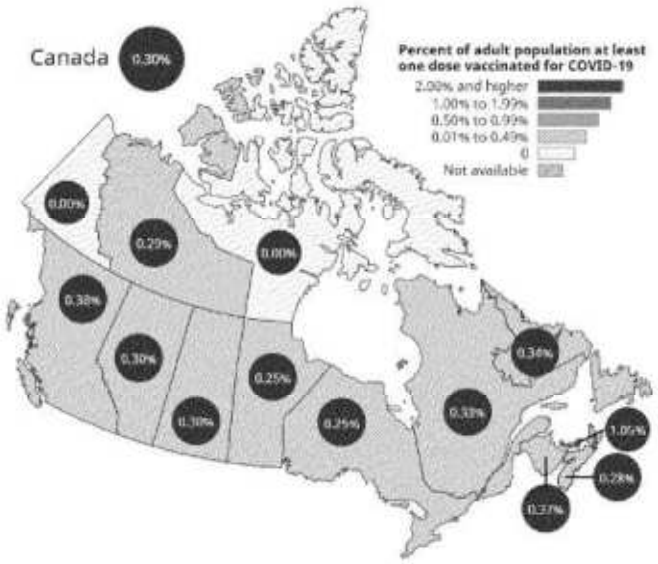
BACKGROUND/reference ...Abridged version of new Canada

COVID-19 Vaccination Coverage report - DRAFT, as of January 2, 2021

[Dev Link: https://infobase-dev.com/covid/vaccination-coverage/index-en.html**]**



- **424,050 doses delivered** to provinces and territories as of January 4, 2021
- **0.30% of the population* received one dose** of COVID-19 vaccines (0% rec'd 2 doses), including:
  - 7.8% of Healthcare workers
  - 0.5% of adults aged 80 years and older
  - 2.2% of adults in group living settings for seniors

Coverage by vaccine product:

- 1.29% of people in Canada have received one dose of the **Pfizer-BioNTech** COVID-19 vaccine, while 0.00% have received two.
- 0.05% of people in Canada have received one dose of the **Moderna** COVID-19 vaccine, while 0.00% have received two.

* Data from Ontario are not included in this value as only information on the total number of people vaccinated was available at the time of report.

Vaccination coverage information on adults in remote and isolated Indigenous and northern communities will be included in future weekly reports when data become available.

COVID-19 Vaccine Safety report – DRAFT, data up to and including January 1, 2021

[Dev Link: https://infobase-dev.com/Benoit/vaccine-safety/index-en.html**]**

- **No safety signals identified,** i.e. AEFIs reported to date considered within the range of expected adverse events
- **115,072** doses administered (9 AEFI/115072 = 0.008%)
- **9 AEFIs:** including 5 serious (with limited information, investigation continuing) and 4 non-serious events
  - All among adults aged 18 to < 50 years old, where age was known
  - All in females, where sex was known
- **In the 9 AEFI reports, there were 65 events reported.**
  - **of 8 adverse events identified in the serious reports:**
    - 2 Anaphylaxis
    - 1 Headache
    - 1 Severe allergic reaction
    - 1 Facial paralysis
    - 1 Chills
    - 1 Syncope
    - 1 Pain in extremity
  - **Most frequently reported non-serious adverse events** were Vaccination site reactions, Nausea, Paraesthesia, Pruritis, Urticaria
  - No deaths were reported.

Notes: one AEFI report (one person) may contain more than one adverse event. That is, one person may have experienced more than one adverse event following immunization. Although there is a possibility an AEFI report (one person) could be reported in both CV and CAEFFISs, the risk of duplicate reporting should be low, given that CV captures reports from manufacturers. Reconciliation between CV and CAEFISS happens on a weekly basis, which enables the detection and removal of duplicates before the weekly report is published on Fridays.

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INTERNAL PHAC AEFI report for January 7, 2021

Summary:

Canada, 13 (0 fatal) AEFIs reported to date; 1 new

- 1 new Canadian AEFI* reported to CVD (no new reported to CAEFISS) as of Jan 7, 2021
    - non-serious, jurisdiction not specified
- To date, 13 reports have been submitted to the Health Portfolio
    - 3 BC; 3 SK; 2 ON; 2 NS; 3 no location specified Canada Vigilance Reports
- No fatalities reported

International, 867 (14 fatal) AEFIs reported to date; 181 new, including one fatal outcome

- none identified as causally associated to vaccine
- Age range from 20 to 90 years of age
- 1 fatal case: 84 year old female with reported AE: Death (US); Cause of death reported: Unknown
- 5 cases of anaphylactic reactions (1 Germany, 1 UK, 3 UK)
- 5 cases of drug hypersensitivity reactions (1 Israel, 1 Portugal, 1 UK, 2 US)
- 1 case of syncope (UK)
- 2 cases of myocardial infarction (US)
- 1 case of seizure and facial paralysis (Germany)
- 12 cases of facial paralysis (3 Israel, 1 UK, 8 US)

No safety signals identified, meaning AEFIs reported to date are considered within the range of expected adverse events.

—

Note re: possibility of double counting in CV/CAEFISS: Although there is a possibility that an AEFI could be reported in both CV and CAEFFISs, in theory, the risk of this should be low, given that CV captures reports from manufacturers. There is a reconciliation between CV and CAEFISS that happens on a weekly basis, which enables the detection and removal of duplicates before the weekly report is published on Fridays. So there is a reasonable level of confidence that each reported AEFI represents a separate event and not duplicate reporting.

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Table 1. Number of COVID-19 vaccine doses administered as of January 2, 2021

Province or territory	Pfizer			Moderna			Total		
	Last week	Previous week	Change	Last week	Previous week	Change	Last week	Previous week	Change
British Columbia *	18,746	NA	-	908	NA	-	19,654	NA	NA
Alberta	NA	NA	-	NA	NA	-	13,383	4,792	8,591
Saskatchewan	3,545	1,783	1,762	0	0	0	3,545	1,783	1,762
Manitoba	3,432	2,177	1,255	0	0	0	3,432	2,177	1,255
Ontario	NA	NA	-	NA	NA	-	37,551	NA	-
Quebec	28,312	17,221	11,091	0	0	0	28,312	17,221	11,091
Newfoundland and Labrador	1,785	1,785	0	0	0	0	1,785	1,785	0
New Brunswick	2,886	2,606	280	0	0	0	2,886	2,606	280
Nova Scotia	2,720	2,218	502	0	0	0	2,720	2,218	502
Prince Edward Island	1,674	1,152	522	0	0	0	1,674	1,152	522
Yukon	0	0	0	0	0	0	0	0	0
Northwest territories	0	0	0	130	0	130	130	0	130
Nunavut	0	0	0	0	0	0	0	0	0
TOTAL	**63,100**	**28,942**	**-***	**1,038**	**0**	**-***	**115,072**	**33,734**	**-****

NA: Not available, data not provided by the province or the territory

* British Columbia data as of January 1, 2021

** Due to differences in the number of PTs that reported each week, total change since last report does not reflect the overall change

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Table 2. Percentage of Canadians aged 16 years and older vaccinated as of January 2, 2021

Province or territory	At least one dose of vaccine				
	Last week		Previous week		Change
	n	%	n	%	%
British Columbia *	19,654	0.4%	NA	NA	-
Alberta	13,383	0.4%	4,792	0.1%	0.2%
Saskatchewan	3,545	0.4%	1,783	0.2%	0.2%
Manitoba	3,432	0.3%	2,177	0.2%	0.1%
Quebec	28,312	0.4%	17,221	0.2%	0.2%
Ontario *	37,551	0.3%	NA	NA	-
Newfoundland and Labrador	1,785	0.4%	1,785	0.4%	0
New Brunswick	2,886	0.4%	2,606	0.4%	<0.1%
Nova Scotia	2,720	0.3%	2,218	0.3%	0.1%
Prince Edward Island	1,674	1.3%	1,152	0.9%	0.4%
Yukon **	0	0.0%	0	0.0%	0.0%
Northwest Territories**	130	0.4%	0	0.0%	0.4%
Nunavut **	0	0.0%	0	0.0%	0.0%
TOTAL**	**115,072**	**0.4%**	**33,734**	**0.2%**	**-¥**

NA: Data not provided by the province or the territory

* BC and ON are excluded from previous week's total; British Columbia data as of January 1, 2021

** As the three territories rolled out only the Moderna vaccine, which is authorised only for those aged 18 years and older, the denominator is the number of people aged 18 years and older.

¥ Due to differences in the number of PTs that reported each week, total change since last report does not reflect the overall change.

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Table 3. Number and percentage of seniors (≥80 years) having received one dose of COVID-19 vaccine as of January 2, 2021

Province or territory	Last week 2020-12-27 to 2021-01-02		Previous week 2020-12-20 to 2020-12-26		Change
	n	%	n	%	%
British Columbia *	2,151	0.9%	NA	NA	-
Alberta	708	0.5%	<5	<0.1%	0.5%
Saskatchewan	<5	<0.1%	<5	<0.1%	0
Manitoba	<5	<0.1%	<5	<0.1%	0
Quebec	1,797	0.4%	1,733	0.4%	<0.1%
Ontario	NA	NA	NA	NA	-
Newfoundland and Labrador	<5	<0.1%	<5	<0.1%	0
New Brunswick	NA	NA	NA	NA	-
Nova Scotia	9	<0.1%	5	<0.1%	<0.1%
Prince Edward Island	0	0%	0	0%	0
Yukon	0	0.0%	0	0.0%	0.0%
Northwest Territories	38	7.5%	0	0.0%	7.5%
Nunavut	0	0.0%	0	0.0%	0.0%
TOTAL**	**4,707**	**0.5%**	**1,743**	**0.2%**	-***

Seniors are defined based on their age, regardless of their residence setting. Therefore, some people counted here may also be counted in Table 4 (congregate living residents)

NA: Data not provided by the province or the territory

* British Columbia data as of January 1, 2021

**Excludes NB and ON for last week's total and excludes BC, ON, and NB for previous week's total

***Due to differences in the number of PTs that reported each week, total change since last report does not reflect the overall change.

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Table 4. Number and percentage of seniors in congregate living residence having received one dose of COVID-19 vaccine as of January 2, 2021

Province or territory	Last week 2020-12-27 to 2021-01-02		Previous week 2020-12-20 to 2020-12-26		Change
	n	%	n	%	%
TOTAL**	7,047	2.2%	2,768	1.0%	-**

Congregate setting residents aged 80 years or over are also counted in Table 3.
NA: Not Available; Data not provided by the province or the territory

* British Columbia data as of January 1, 2021

**Excludes ON for last week's total and BC and ON for previous week's total

***Due to differences in the number of PTs that reported each week, total change since last report does not reflect the overall change.

Table 5. Number and percentage of healthcare workers having received one dose of COVID-19 vaccine as of January 2, 2021

Province or territory	Last week 2020-12-27 to 2021-01-02		Previous week 2020-12-20 to 2020-12-26		Change
	n	%	n	%	%
TOTAL	69,980	7.8%	30,646	3.8%	-**

NA: Not Available; Data not provided by the province or the territory

* BC and ON are excluded from previous week's total; British Columbia data as of January 1, 2021

**Due to differences in the number of PTs that reported each week, total change since last report does not reflect the overall change

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From: McDonald, Alexa (PHAC/ASPC) on behalf of CCMOH SECRETARIAT / CMHC (PHAC/ASPC)
Sent: 2021-07-02 11:54 AM
To: [redacted] (Ext.); Njoo, Howard (PHAC/ASPC) [redacted] Sharma, Supriya (HC/SC); Tam, Dr Theresa (PHAC/ASPC); Wong, Tom (SAC/ISC); [redacted] (Ext.); Robinson, Kerry (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Vincent Beswick-Escanlar
Cc: NACI / CCNI (PHAC/ASPC); Bedward, Cristina (PHAC/ASPC); CCMOH SECRETARIAT / CMHC (PHAC/ASPC); Robinson, Kerry (PHAC/ASPC)
Subject: Embargo Copy: NACI Recommendations on the Use of COVID-19 Vaccines / CCNI Recommandations sur l'utilisation des vaccins contre la COVID-19
Attachments: CONFIDENTIEL_Summary of NACI Stmt_Myocarditis_FINAL_FR.pdf; CONFIDENTIAL_NACI Stmt_Myocarditis_FINAL_EN.pdf; CONFIDENTIAL_Summary of NACI Stmt_Myocarditis_FINAL_EN.pdf; CONFIDENTIEL_NACI Stmt_Myocarditis_FINAL_FR.pdf

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**Not for further distribution at this time*

Dear SAC members,

Please see attached embargoed copies of the updated NACI recommendations on the Use of COVID-19 vaccines. **Please note this material is embargoed until its public release later today.** The SAC Secretariat will share the live web links once publically available.

Thank you,
SAC Secretariat

****

(le français suit)

Dear Colleagues,

Please find attached an embargoed copy of the recently approved National Advisory Committee on Immunization's (NACI) ***Recommendations on the use of COVID-19 vaccines.***

Also included in this embargoed package is the ***Summary of NACI Statement of July 2, 2021.***

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Please note this electronic copy is for your reference and information only and is **not for further distribution outside of your organisation at this time.** This guidance will be published on PHAC's website on July 2, 2021.

Thank you,

Madame, Monsieur,

Veuillez trouver ci-joint une copie sous embargo et récemment approuvée de la ***Recommandations sur l'utilisation des vaccins contre la COVID-19*** du Comité consultatif national de l'immunisation (CCNI).

Ce paquet sous embargo comprend également le ***résumé de la déclaration du CCNI du 2 juillet 2021.***

Veuillez noter que cette copie électronique est destinée à votre référence et à votre information uniquement et qu'elle ne doit pas être distribuée à l'extérieur de votre organisation pour le moment. Cette orientation sera publiée sur le site Web de l'ASPC le 2 juillet 2021.

Merci

National Advisory Committee on Immunization (NACI) Secretariat/
Secrétariat du Comité consultatif national de l'immunisation (CCNI)
Public Health Agency of Canada / Agence de la santé publique du Canada
Web: www.phac-aspc.gc.ca/naci-ccni

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An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Recommendations on the use of COVID-19 Vaccines

Published: July 2, 2021

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JULY 2, 2021

PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Public Health Agency of Canada | Agence de la santé publique du Canada

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PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence-based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

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TABLE OF UPDATES

This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, as evidence on these vaccines and COVID-19 evolves, and as recommendations from NACI evolve based on this evidence. This table summarizes the updated information provided in the current version of this document since the publication of the last version of the document on June 17, 2021.

A complete list of changes to this document can be found in the Table of updates: Recommendations on the use of COVID-19 vaccines web page. Complete previous versions of this document are archived and are available through the National Advisory Committee on Immunization (NACI): Statements and publications web page under COVID-19.

Section	Update	Date
Vaccines: Uncommon, rare, and very rare adverse events	The section on myocarditis and pericarditis following vaccination with mRNA vaccines has been updated, and a section on capillary leak syndrome (CLS) following vaccination with AstraZeneca COVID-19 vaccine has been added.	2021-07-02
Vaccines: Precautions	A section on myocarditis and/or pericarditis following mRNA COVID-19 vaccination has been added. As a precautionary measure, the second dose in the mRNA COVID-19 vaccination series should be deferred in individuals who experience myocarditis or pericarditis following the first dose of an mRNA COVID-19 vaccine until more information is available. NACI will continue to monitor the evidence and update recommendations as needed.	2021-07-02
Contraindications	A history of CLS has been added as a contraindication to vaccination with AstraZeneca/COVISHIELD COVID-19 vaccine	2021-07-02
Recommendations	To assist with information consent, the rationale for NACI recommendation (#1) on the use of mRNA vaccines now includes information on very rare reports of myocarditis and pericarditis following mRNA vaccination, noting that cases have been reported most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose.	2021-07-02
Recommendations	NACI recommendation (#11) on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents has been updated to include guidance on informed consent in reference to	2021-07-02

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Section	Update	Date
	very rare reports of myocarditis and pericarditis following mRNA vaccination as noted above.	
Table 5. Vaccination considerations for types of COVID-19 vaccines authorized for use in Canada	Updated content to reflect changes to guidance as noted above.	2021-07-02

SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT

The following highlights key, current information for immunization providers on COVID-19 vaccines. The evidence on COVID-19 disease and vaccines is evolving. Evidence from clinical trial data is limited due to limitations in the size and duration of follow-up of trial populations. However, clinical trials and studies in the real-world setting are ongoing. NACI will continue to monitor the evidence and update its recommendations as needed. Please refer to the remainder of the Statement for details.

What

Disease

- Novel coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Genetic mutations in the SARS-CoV-2 virus have been identified ("variants"), some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.
- Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors that may intersect. Risk factors for exposure and severe disease may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations.

Currently authorized and available vaccines
(Pfizer BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine)

- mRNA vaccines are authorized for use in Canada for individuals 12 years of age and older (Pfizer-BioNTech COVID-19 vaccine) or 18 years of age and older (Moderna COVID-19 vaccine).
- Non-replicating viral vector vaccines are authorized for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine and Janssen COVID-19 vaccine).
- In clinical trials, all COVID-19 vaccines are efficacious in the short-term against symptomatic, confirmed COVID-19 disease; trials are ongoing. mRNA COVID-19 vaccines have demonstrated high efficacy (≥94%). The AstraZeneca COVID-19 vaccine

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has demonstrated an average efficacy of approximately 62% in those 18-64 years of age. In adults 65 years of age and older who received one dose of AstraZeneca, real-world observational data of vaccine effectiveness have shown a reduction in the risk of symptomatic disease and hospitalization. The Janssen COVID-19 vaccine has demonstrated efficacy of 67% against confirmed symptomatic moderate to severe/critical COVID-19 infection based on trials conducted in South Africa and Brazil while B.1.351 (Beta) variant of concern (VOC) and P.2 (Zeta) variant of interest (VOI) were circulating, respectively. There is currently limited evidence on the duration of protection and on the efficacy of these vaccines in reducing transmission of SARS-CoV-2, although studies are ongoing. Evidence of protection against asymptomatic SARS-CoV-2 infection is emerging for the mRNA and Janssen vaccines.

- Evidence of varying protection offered by COVID-19 vaccines against SARS-CoV-2 variants is evolving. To date, evidence has emerged that the Pfizer-BioNTech and AstraZeneca vaccines offer protection against the B.1.1.7 (Alpha) VOC . Furthermore, there is emerging evidence that both vaccines also offer good protection against infection with the B.1.617.2 (Delta) VOC after the second dose and good protection against hospitalization after the first dose. There is evidence that the Janssen vaccine offers some protection against the B.1.351 (Beta) VOC as well as the P.2 (Zeta) VOI. There is evidence that the AstraZeneca vaccine does not offer protection against the B.1.351 (Beta) VOC.
- For all vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. In clinical trials of mRNA vaccines, some adverse events, including fever, are more frequent after the second dose; this was not the case with the AstraZeneca COVID-19 vaccine.
- Very rare cases of a specific syndrome that involves serious blood clots (at unusual sites such as cerebral venous sinus thrombosis) associated with thrombocytopenia have been reported after vaccination with viral vector vaccines. These cases often occur between 4 and 28 days after receipt of the vaccine. Early identification and appropriate treatment are critical. Investigations to better understand this syndrome, often referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), are ongoing. Individuals who have experienced venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 vaccine.
- Very rare cases of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines have been reported, most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose. The majority of reported cases were mild and the individuals tend to recover quickly. Investigations are ongoing. As a precautionary measure, individuals who have experienced myocarditis or pericarditis following vaccination with a first dose of an mRNA COVID-19 vaccine should defer the second dose in the vaccination series until more information is available. NACI will continue to monitor the evidence and update recommendations as needed.
- Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine [1-3]. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia. Individuals with a history of CLS should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine.

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- There is currently minimal evidence to inform on differences in vaccine efficacy, effectiveness, or safety between individuals with and those without prior evidence of SARS-CoV-2 infection at the time of vaccination.

Who

NACI makes the following recommendations:

A complete series with an mRNA COVID-19 vaccine should be preferentially offered to individuals in the authorized age group without contraindications to the vaccine.

A viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop.

A complete vaccine series with a currently authorized COVID-19 vaccine may be offered to:

- Individuals in the authorized age group without contraindications to the vaccine who have had previously polymerase chain reaction (PCR)-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.

NACI also recommends that:

- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.
- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded or remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions. Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.
- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, and seniors living in congregate care settings) is recommended.

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NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization:

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.
- Jurisdictions should ensure close and rapid monitoring of safety, coverage and effectiveness of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.
- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

How

- Currently authorized and available COVID-19 vaccines are administered intramuscularly in a two-dose schedule (Pfizer-BioNTech, Moderna, and AstraZeneca) or in a one-dose schedule (Janssen).
- When the first dose in a COVID-19 vaccine series is an mRNA vaccine, the same mRNA vaccine product should be offered for the subsequent dose if readily available. When the same mRNA vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended in that age group can be considered interchangeable and should be offered to complete the series.
- When the first dose in a COVID-19 vaccine series is the AstraZeneca/COVISHIELD vaccine, either the AstraZeneca/COVISHIELD vaccine or an mRNA vaccine product may be offered for the subsequent dose to complete the series; however an mRNA vaccine product is preferred as a subsequent dose due to emerging evidence including the possibility of better immune response, and the safety of heterologous schedules. Individuals who have already received two doses of the AstraZeneca/COVISHIELD vaccine are considered protected and do not require further vaccination.
- Serologic testing is not needed before or after receipt of a COVID-19 vaccine to assess susceptibility to SARS-CoV-2 or immune response to the vaccine.
- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines at this time, unless other vaccines are required for post-exposure prophylaxis.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

Why

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption in Canada and worldwide.
- The authorized COVID-19 vaccines that are recommended for use by NACI in this Statement have been shown to be safe (although very rare cases of VITT reported following vaccination with the viral vector COVID-19 vaccines), efficacious against symptomatic laboratory confirmed COVID-19, and appear to protect against severe disease, hospitalization and death due to COVID-19.

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I. INTRODUCTION

The overall goal of Canada's pandemic response is to minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic. The goal of Canada's COVID-19 immunization response is: To enable as many Canadians as possible to be immunized against COVID-19 as quickly as possible, while ensuring that high risk populations are prioritized.

This guidance document will provide recommendations on the use of authorized COVID-19 vaccines as they are approved and available for use in Canada, and as evidence on these vaccines evolves.

There are four COVID-19 vaccines currently authorized for use in Canada:

1. The Pfizer-BioNTech COVID-19 vaccine was authorized for use in Canada on December 9, 2020 for ages 16 and up. On May 5, 2021, Health Canada expanded the Interim Order authorization for the Pfizer-BioNTech COVID-19 vaccine to include 12 to 15 year olds.
2. The Moderna COVID-19 vaccine was authorized for use in Canada for those ages 18 and above on December 23, 2020.
3. The AstraZeneca COVID-19 vaccine was authorized for use in Canada for those ages 18 and above on February 26, 2021.
    - Health Canada authorized two manufacturers to produce this vaccine developed by AstraZeneca and Oxford University: AstraZeneca and Serum Institute of India (SII). NACI has not specifically reviewed evidence for the SII vaccine, but Health Canada has deemed SII and AstraZeneca vaccines to be comparable. Authorization of the SII COVID-19 vaccine (COVISHIELD) was based on its comparability to the AstraZeneca COVID-19 vaccine as determined by evaluation and direct comparison of manufacturing processes and controls and the quality characteristics of the two products. The results of this comparison by Health Canada determined that the two products were sufficiently similar and that the efficacy, immunogenicity and safety of COVISHIELD could be inferred from the non-clinical and clinical studies from the AstraZeneca COVID-19 vaccine.
4. The Janssen COVID-19 vaccine was authorized for use in Canada for those ages 18 and above on March 5, 2021.

The evidence on COVID-19 and COVID-19 vaccines has been rapidly evolving. To date, NACI has published the following evidence-informed guidance:

1. Research priorities for COVID-19 vaccines to support public health decisions (archived) to inform clinical trials of candidate COVID-19 vaccines to protect against infection, serious illness, and deaths caused by SARS-CoV-2.
2. Preliminary guidance on key populations for early COVID-19 immunization to plan for the efficient, effective, and equitable allocation of COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.
3. Guidance on the prioritization of initial doses of COVID-19 vaccine(s) for the efficient and equitable prioritization of initial doses of COVID-19 vaccines to assist with the planning for allocation of the first COVID-19 immunization programs.
4. Guidance on the prioritization of key populations for COVID-19 immunization to provide guidance for the equitable, ethical, and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others.

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5. Rapid response: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada (archived) to maximize the number of individuals benefiting from the first dose of vaccine by extending the interval for the second dose up to four months after the first. This was followed by a more comprehensive NACI statement (archived) providing a detailed overview of the evidence and considerations leading to NACI's recommendation.
6. Rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults (archived) guidance developed in response to the investigation of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) [hereafter referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)] following vaccination with AstraZeneca COVID-19 vaccine is investigated further.
7. Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 to 18 years of age (recommending that a complete series with a Pfizer-BioNTech COVID-19 vaccine should be offered to individuals 12 to 18 years of age without contraindications to the vaccine).
8. Rapid response: Interchangeability of authorized COVID-19 vaccines (archived) to provide advice on the interchangeability of authorized COVID-19 vaccines in a two-dose primary series schedule for COVID-19 immunization in Canada.
9. Recommendations on the use of COVID-19 vaccines (archived) initially published on December 12, 2020 and updated iteratively as new evidence becomes available and with the authorization of additional COVID-19 vaccines. This statement reflects the most up to date guidance.

Guidance Objective

The objective of this advisory committee statement is to provide evidence-informed guidance on the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada. This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, and as the evolution of evidence on these vaccines or the pandemic situation warrants changes in guidance. In this guidance document, the evidence and rationale for recommendations as well as current knowledge gaps will be summarized. Evidence summaries on vaccine characteristics for specific COVID-19 vaccines will be included in appendices.

II. METHODS

Details of NACI's recommendation development process can be found elsewhere [4, 5].

In brief, the broad stages in the preparation of this NACI advisory committee statement included:

1. Knowledge synthesis
2. Synthesis of the body of evidence of benefits and harms, considering the quality of the synthesized evidence and magnitude and certainty of effects observed across the studies
3. Translation of evidence into recommendations.

In order to develop comprehensive, appropriate immunization program recommendations, NACI considers a number of factors. In addition to critically appraising evidence on burden of disease and vaccine characteristics such as safety, efficacy, immunogenicity and effectiveness, NACI uses a published, peer-reviewed framework and evidence-informed tools to ensure that issues related to ethics, equity, feasibility, and acceptability (EEFA) are systematically assessed and

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integrated into its guidance [5]. The NACI Secretariat applied this framework with accompanying evidence-informed tools (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, and Acceptability Matrix) to systematically consider these programmatic factors for the development of clear, comprehensive, appropriate recommendations for timely, transparent decision-making. For details on the development and application of NACI's EEFA Framework and evidence-informed tools (including the Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, and Acceptability Matrix), please see https://doi.org/10.1016/j.vaccine.2020.05.051.

For this advisory committee statement, NACI used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to develop population-focused recommendations. Further information on this framework can be found in the GRADE handbook, available at: https://training.cochrane.org/resource/grade-handbook

NACI reviewed and approved the key policy questions used to guide recommendation development on November 25, 2020 and rated the outcomes for their importance for decision-making. With evolving evidence, NACI rated outcomes again on March 21, 2021. The Canadian Immunization Committee (CIC) provided feedback on the key policy questions to ensure alignment with program needs. Important ethical considerations relating to the key policy questions were presented on November 26, 2020, December 15, 2020, January 26, 2021 and April 6, 2021 to the PHAC Public Health Ethics Consultative Group, who provided an assessment of ethical considerations that are relevant to the development of recommendations. Knowledge synthesis and quality appraisal were performed by the NACI Secretariat for unpublished clinical trial evidence and were informed by NACI's rating of the outcomes. Unpublished data from Phase 1, 2, and 3 clinical trials were presented to the High Consequence Infectious Disease Working Group and NACI for discussion. Proposed recommendations were then presented and approved at emergency NACI meetings. The description of relevant considerations, rationale for specific decisions, and knowledge gaps are described in the text.

Key Dates

- Pfizer-BioNTech COVID-19 vaccine was discussed on December 4, 2020 and related recommendations were approved on December 7, 2020.
- The Moderna COVID-19 vaccine was discussed on December 14, 2020 and related recommendations were approved on December 17, 2020.
- The AstraZeneca COVID-19 vaccine was discussed on January 19, 28, February 5, and February 24, 2021 and related recommendations were approved on February 24, 2021.
- Considerations regarding an extended interval between authorized vaccine doses in the context of limited vaccine supplies, and clarifications to recommendations for populations who were either excluded from or were represented by small numbers of participants in clinical trials were discussed on January 7, 2021 and were approved on January 8, 2021.
- Additional evidence on an extended interval of 4 months between authorized vaccine doses in the context of limited vaccine supplies was reviewed on February 8, 19, and 24-25, 2021. Related recommendations were approved on March 1, 2021. Between March 25 and March 28, 2021, NACI members revisited these recommendations as they relate to specific population groups.
- Additional evidence from observational studies of effectiveness of the AstraZeneca vaccine in those 65 years of age and over was reviewed on March 10, 2021. Related recommendations were approved on March 13, 2021.
- Evolving evidence of VITT following the use of AstraZeneca COVID-19 vaccine was first reviewed on March 24, 2021 and related recommendations were approved on March 28, 2021. New evidence, including the Health Canada's safety assessment report issued on

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April 14, 2021, was formally reviewed on April 13, 15, 17 and 20, 2021. Updated recommendations were approved on April 20, 2021.

- The Janssen COVID-19 vaccine was discussed on March 16, 25 and April 13, 26, 2021, and recommendations were approved on April 30, 2021.
- Evolving evidence on extended intervals was reviewed on May 11 and 13, 2021. NACI updated the related recommendation on May 13, 2021 in the context of increasing COVID-19 vaccine supplies.
- Additional evidence in populations either excluded from, or included in small numbers, in clinical trials was reviewed on May 4 and 13, 2021. Related recommendations for COVID-19 vaccination in those who are immunosuppressed, have an autoimmune condition, are pregnant, or are breastfeeding were revised and approved on May 13, 2021.
- NACI reviewed the available evidence on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 to 15 years of age on May 9, 2021 and approved the related recommendation on May 11, 2021.
- Evidence on mixed COVID-19 vaccine schedules was presented and reviewed by NACI on May 26, 2021 and related recommendations were approved on May 30, 2021. Emerging evidence was reviewed on June 9 and the related recommendation on interchangeability in a vaccine series when the first dose is an AstraZeneca/COVISHIELD COVID-19 vaccine was revised and approved on June 11, 2021.
- NACI reviewed its recommendation on simultaneous administration of COVID-19 vaccines with other vaccines and updated its recommendation on June 9, 2021.
- Evidence on myocarditis and pericarditis was presented and reviewed by NACI on May 18, June 1, June 15, June 21, and June 24, 2021. NACI approved updated information for inclusion in NACI's guidance on June 27, 2021.

III. EPIDEMIOLOGY

Information on COVID-19 is continually evolving. The following section will describe the current basis of knowledge, with an emphasis on the best available Canadian data where possible. To access the most recent updates to specific elements, please refer to the links below.

Disease description

Infectious agent

COVID-19 is caused by the SARS-CoV-2, which was first recognized in Wuhan, China in December 2019.

Transmission

Current evidence suggests that SARS-CoV-2 is spread through respiratory droplets and aerosols created when an infected person coughs, sneezes, sings, shouts, or talks. A person may be infectious for up to three days before showing symptoms.

More information on the transmission of SARS-CoV-2 can be found on the PHAC webpages for COVID-19: Main modes of transmission and COVID-19 signs, symptoms and severity of disease: A clinician guide

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Variants of concern

Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.

More information on the variants of concern (VOC) reported in Canada is available in the COVID-19 epidemiology update. The COVID-19 Weekly Epidemiological Update by the World Health Organization provides a summary on the global distribution and emerging evidence on VOC and variants of interest (VOI). Differences between VOC and VOI are available from SARS-CoV-2 variants: National definitions, classifications and public health actions.

NACI will continue to monitor the epidemiology and evidence pertaining to VOC and COVID-19 vaccines.

Risk factors

Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or occupational settings), and some populations are at increased risk of severe disease and outcomes (e.g., hospitalization and death) due to various biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., socioeconomic status, belonging to a racialized population) factors that may intersect. Exposure and risk of severe disease factors may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations characterized by increased rates of infection and disease, severe illness, hospitalizations, and/or deaths.

Please see NACI's Advisory Committee Statement on Key Populations for Early COVID-19 Immunization and the Equity Matrix [6] for a summary of inequities associated with COVID-19, potential reasons for and intersections between these inequities, and suggested interventions to reduce inequities and improve access to vaccines. NACI's Guidance on the prioritization of key populations for COVID-19 immunization builds on the foundational framework for the equitable, ethical and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others. This guidance was informed by evolving evidence on risk factors for COVID-19.

Table 1 summarizes populations at risk of severe outcomes from COVID-19 (hospitalization and/or mortality) based on the results of an updated rapid review of evidence [7] from studies in Organisation for Economic Co-operation and Development (OECD) countries, as well as populations at increased risk of exposure to COVID-19 (due to inability to physically distance and/or reduced access to infection prevention and control measures) identified, in part, through Canadian reports (epidemiological or analytic).

The review by the Alberta Research Centre for Health Evidence (ARCHE) found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with age 60-69 years versus <60 years [7]. A previous review by ARCHE found a moderate certainty of evidence for at least a 5-fold increase in mortality and hospitalization with age over 70 years (versus 45 years and younger) [8]. Studies treating age on a continuum or across small increments consistently found that risks for hospitalization and mortality increased with increasing age (e.g., approximately 2-6% and 5-10% relative increase in risk per year) [7].

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The ARCHE review found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with a small number of medical conditions (classified as Level 1 in Table 1) [7]. The review found a low certainty of evidence for at least a 2-fold increase in mortality from COVID-19, and/or a low or moderate certainty of evidence for at least a 2-fold increase in hospitalization for a longer list of medical conditions (classified as Level 2). Individuals with two or more medical conditions were found to have at least a 2-fold increase in hospitalization and mortality from COVID-19 (moderate certainty of evidence). Similarly, in populations 21 years of age and younger, individuals with two or more medical conditions were found to have at least a 2-fold increase in hospitalizations from COVID-19 (moderate certainty of evidence). However, there is no direct evidence on which combination of medical conditions increase this risk [7].

Caution should be taken when interpreting evidence of low certainty (e.g., for medical conditions listed as Level 2). As evidence accumulates, observed associations may change. For example, a previous rapid review by ARCHE [9] found low certainty evidence for at least a 2-fold increase in hospitalization or mortality for males, people with liver disease, and people with heart failure. As evidence has accumulated, there is now stronger evidence for little-to-no increased association of severe outcomes in these populations. The list of medical conditions included in Table 1 may not be comprehensive as it is based only on evidence from published studies included in the ARCHE review.

Table 1. Summary of risk factors for severe outcomes from COVID-19 and increased risk of exposure to COVID-19

Increased risk of severe outcomes from COVID-19 (hospitalization/mortality)[a]	Increased risk of exposure to COVID-19 [7] (e.g., due to inability to physically distance/reduced access to IPC)[b]
Increasing age (strong evidence) (based on moderate certainty of evidence of ≥2-fold increase in mortality) • ≥60 years (particularly ≥ 70 years) [7]	• Residents and staff of congregate living settings that provide care for seniors • Frontline healthcare workers • Adults in Indigenous communities • Residents and staff of other congregate living settings (e.g., quarters for migrant workers, shelters, correctional facilities, group homes) • Adults in racialized and marginalized communities • First responders (e.g., police, firefighters) • Frontline essential workers who cannot work virtually
Medical conditions – Level 1 (strong evidence) [7] (based on moderate or high certainty evidence of ≥2-fold increase in mortality) • Down syndrome • End-stage kidney disease • Epilepsy • Motor neuron disease, multiple sclerosis, myasthenia gravis, Huntington's disease[d] • Type 1 and 2 diabetes	
Medical conditions – Level 2 (limited evidence) [7] **Level 2a** (based on low certainty of evidence of ≥2-fold increase in mortality • Cerebral palsy • Major psychiatric disorder (schizophrenia, schizoaffective disorder, or bipolar disorder); in combination with prescription drug use for the condition in the past 6 months • Obesity class III (BMI ≥40 kg/m^2)	

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• Parkinson's disease • Sickle cell disease or severe immunodeficiency, transplant (any type) • Solid organ transplant • Recent bone marrow or stem cell transplant • Metastatic cancer • Recent/current chemotherapy or radiotherapy **Level 2b** (based on low or moderate certainty of evidence of ≥2-fold increase in hospitalization) • Previous cerebrovascular accident • Pregnancy (any stage) • Frailty (among community and non-community dwelling people; measured on scales that include items such as weight loss, exhaustion, physical activity, walking speed, grip strength, overall health, disability, presence of disease, dementia, falls, mental wellbeing) • Vasculitis • Obesity – all classes (BMI >30 kg/m^2)	
Increased risk of severe outcomes (hospitalization/mortality)[c] and Increased risk of exposure [7]	
• Long-term care residents • Visible minority groups (includes mainly South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean, Japanese)	

[a] Identified through rapid review of evidence from OECD countries for an independent association with severe outcomes from COVID

[b] Identified, in part, through Canadian epidemiological reports

[c] Identified through rapid review of Canadian studies that may have an association with hospitalization and mortality from COVID-19. These studies may not have accounted for other covariates.

[d] These conditions were grouped within a single study; evidence for the individual conditions is either unavailable or of lower certainty.

The list of medical conditions in Table 1 may differ from those in other jurisdictions due to differences in local epidemiology and differing levels of evidence considered.

The evidence on risk factors for COVID-19 continues to evolve.

Spectrum of clinical illness

The median incubation period for non-variant SARS-CoV-2 has been estimated to be 5 to 6 days from exposure to symptom onset, with most individuals (97.5%) developing symptoms within 11.5 days of exposure. The incubation period ranges from 1 to 14 days.

Clinical presentation and symptoms of COVID-19 vary in frequency and severity. To date, there is no list of symptoms that has been validated to have high specificity or sensitivity for COVID-19.

More information on the spectrum of clinical illness is available on the PHAC webpage for COVID-19 signs, symptoms and severity of disease: A clinician guide.

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Disease incidence

Global
Updated international data on COVID-19 cases and deaths is available at:
https://health-infobase.canada.ca/covid-19/international/

Weekly epidemiological updates highlighting key global, regional and country-level data on COVID-19 cases and deaths are available from the World Health Organization (WHO) at:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

National
Updated national, provincial and territorial-level data on COVID-19 cases and deaths in Canada over time is available from the PHAC webpage on Coronavirus disease (COVID-19): Outbreak update.

IV. VACCINES

The following section summarizes information about COVID-19 vaccines authorized for use in Canada. More detailed vaccine-specific information is included in Appendices A through D. The current landscape of all candidate COVID-19 vaccines in clinical evaluation can be found on the WHO webpage Draft landscape of COVID-19 candidate vaccines. Under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, Health Canada can make regulatory decisions for COVID-19 vaccines that have completed Phase 3 clinical trials for authorized use in Canada.

Most vaccine candidates in development that may become authorized for use in Canada use various technologies to deliver SARS-CoV-2 spike protein to vaccine recipients. This protein is expressed on the surface of the SARS-CoV-2 virus and is a major target for binding and neutralizing antibodies as well as cell-mediated immune responses.

mRNA vaccines
COVID-19 vaccines that use messenger RNA (mRNA) platforms contain modified nucleotides that code for the SARS-CoV-2 spike protein. A lipid nanoparticle formulation delivers the mRNA into the recipient's cells. Once inside the cytoplasm of a cell, the mRNA provides instructions to the cell's protein production machinery to produce the trans-membrane spike protein antigen that becomes anchored on the cell's external surface. The mRNA does not enter the nucleus of the cell and does not interact with, or alter, human DNA. The immune system is engaged by both the transmembrane spike protein and immune receptors carrying spike antigens to induce humoral and cellular immune responses. The mRNA, lipid nanoparticle, and spike protein are degraded or excreted within days to weeks from time of immunization. mRNA vaccines are not live vaccines and cannot cause infection in the host.

Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

Non-replicating viral vector vaccines
COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells. The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease (i.e., they are non-replicating). Once

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inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell. The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd). The Janssen vaccine uses a modified human adenovirus serotype 26 vector (Ad26).

IV.1 Preparations of COVID-19 vaccines authorized and available for use in Canada

Table 2. COVID-19 vaccines available for use in Canada

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 / COVISHIELD Vaccine	Janssen COVID-19 Vaccine
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)
Date of authorization in Canada	December 9, 2020 (16 years of age and older); May 5, 2021 (12 years of age and older)	December 23, 2020	February 26, 2021	March 5, 2021
Authorized ages for use	12 years of age and older	18 years of age and older	18 years of age and older	18 years of age and older
Dose	0.3 mL (30 mcg of mRNA)[a]	0.5 mL (100 mcg of mRNA)	0.5 mL (5×10^{10} viral particles)	0.5 mL (5×10^{10} viral particles)
Authorized Schedule[b]	2 Doses, 3 weeks apart	2 Doses, 4 weeks apart	2 Doses, 4 to 12 weeks apart	1 Dose
Route of administration	IM	IM	IM	IM
Nature of the antigen	Transmembrane prefusion spike protein	Transmembrane prefusion spike protein	Transmembrane spike protein	Transmembrane prefusion spike protein
Adjuvant (if present)	None	None	None	None
Primary storage requirements pre-puncture[c]	-80°C to -60°C	-25°C to -15°C[d]	+2°C to +8°C	+2°C to +8°C
Additional storage options pre-puncture[c]	Frozen vials: -25°C to -15°C for up to 2 weeks[e] Thawed under frigeration: 1 month at +2°C to +8°C Thawed at room temperature: 2 hours up to +25°C	30 days at +2°C to +8°C AND/OR 24 hours at +8°C to +25°C	+2°C to +8°C	+2°C to +8°C
Diluent	Yes	No	No	No
Usage limit post-puncture	6 hours at +2°C to +25°C[f]	24 hours at +2°C to +25°C	6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to +8°C.	3 hours at room temperature (up to +25°C) OR 6 hours at +2°C to +8°C
Formats available	Multi-dose vial (6 doses)[a], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (8-and 10-dose presentations), preservative-free	Multi-dose vial (5 doses), preservative-free

Abbreviations: ChAd: Chimpanzee adenovirus; Ad26: modified human adenovirus 26; IM: Intramuscular; mRNA: Messenger ribonucleic acid

[a] After dilution, one vial contains 6 doses of 0.3 mL each. However, vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in the product monograph supersedes the number of doses stated on vial labels and cartons. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial. Refer to the product monograph available through Health Canada's Drug Product Database for choice of diluent, dilution instructions and type of syringes which can be used to extract 6 doses from a single vial.

[b] Authorized schedule per the product monograph. For NACI recommendations on intervals between doses, refer to Table 3.

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[c] Protected from light during storage
[d] Do not store on dry ice or below -40°C.
[e] Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.
[f] After dilution, vaccine must be used within 6 hours.

IV.2 Efficacy and Effectiveness

Due to the availability of only short-term clinical trial data, the duration of protection provided by COVID-19 vaccination is currently unknown. However, studies are ongoing.

The following section highlights key efficacy and effectiveness data for authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and the authorized viral vector-based COVID-19 vaccines (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine) only. For additional details regarding trial design, including study population, length of follow-up, and efficacy for the authorized and available vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine).

Efficacy against symptomatic COVID-19 disease
The currently authorized mRNA COVID-19 vaccines have been shown to be highly efficacious in the short term against confirmed symptomatic COVID-19 disease (presence of one or more symptoms plus laboratory confirmation of SARS-CoV-2 infection). The authorized two-dose mRNA vaccines schedules are similarly efficacious in adults with one or more comorbidities, as well as in adolescents (Pfizer-BioNTech COVID-19 vaccine), younger adults and older adults.

In clinical trials, AstraZeneca COVID-19 viral vector vaccine has shown moderate short-term efficacy against symptomatic COVID-19 disease (presence of at least one pre-defined COVID-19 symptom plus laboratory confirmation of SARS-CoV-2 infection) in adults 18–64 years of age, at least two weeks after receiving the full series of two standard doses of the vaccine. Clinical trial data show that efficacy increased as the interval between doses increased. At present, there are insufficient clinical trial data in adults ≥65 years of age to assess vaccine efficacy in this age group. The vaccine is similarly efficacious in adults ≥18 years of age with and without pre-defined comorbidities (presence of one or more mild to moderate and controlled cardiovascular disease, respiratory disease, diabetes or obesity). In the initial absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized in Appendix C. These studies provide effectiveness estimates following the first dose of AstraZeneca vaccine and have shown a reduction in the risk of symptomatic disease and hospitalization that appears to reach a comparable level to that observed among persons of similar age who received one dose of mRNA vaccine.

The Janssen COVID-19 vaccine demonstrates moderate efficacy against symptomatic confirmed moderate to severe/critical COVID-19 infection from 14 days and 28 days post-vaccination, where the definition of moderate disease includes the presence of one to two or more of a relatively broad range of COVID-19 compatible signs and symptoms plus laboratory confirmation of SARS-CoV-2 infection. The point estimates of vaccine efficacy at these two time points across a variety of age groups are similar to the overall estimate, including among study participants ≥65 years of age who comprised approximately 20% of the study population. Point estimates of vaccine efficacy at 14 days post-vaccination are comparable in study participants with and without one or

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more comorbidities. In contrast, the point estimate of efficacy in participants with comorbidities is somewhat lower at 28 days post-vaccination. Efficacy for Janssen vaccine was based on clinical trials that were conducted in countries with widely circulating VOCs (South Africa and Brazil), which may have impacted its overall efficacy. This is in contrast to the clinical trials for other authorized COVID-19 vaccines.

The clinical trial data demonstrates that the authorized mRNA COVID-19 vaccines are efficacious over the short-term in individuals with or without evidence of prior SARS-CoV-2 infection. However, participants with laboratory-confirmed (using a nucleic acid amplification test, such as RT-PCR) SARS-CoV-2 infection prior to enrollment were excluded from the trials and the number of trial participants with evidence of previous infection (as defined by trial protocol) who had confirmed symptomatic COVID-19 disease during the trials were small; therefore, the efficacy in this population and how it compares to those without evidence of previous infection is unknown at this time. The efficacy of the Janssen COVID-19 vaccine in those with evidence of prior infection is inconclusive at this time due to small sample size, and this outcome has not been assessed for AstraZeneca COVID-19 vaccine.

The first dose of the authorized COVID-19 vaccines has been shown to offer at least short-term protection against confirmed COVID-19 disease. For mRNA vaccines, the highest efficacy is seen after the second dose is administered. There is currently no available evidence on medium- and long-term efficacy of the authorized COVID-19 vaccines, however trials are ongoing, and this Statement will be updated as evidence emerges.

Efficacy and effectiveness against severe disease

The clinical trials of the authorized and available COVID-19 vaccines assessed efficacy against severe COVID-19 disease, but not all provided sufficient data to be able to assess the efficacy against hospitalizations or deaths.

The authorized mRNA and the Janssen COVID-19 vaccines appear efficacious against severe COVID-19 outcomes based on clinical trial data used for authorization (severe outcomes were defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death). However, the number of severe cases that have been observed to date was small in the Pfizer-BioNTech clinical trial in participants 16 years of age and older, and was too small in the AstraZeneca clinical trials to assess efficacy. There were no severe cases identified in adolescents 12 to 15 years of age in the Pfizer-BioNTech clinical trial. Efficacy against hospitalization was not assessed in the clinical trials of the mRNA vaccines, but evidence from the clinical trials involving the viral vector vaccines is suggestive of a protective effect against hospitalization. To date there have been very few COVID-19 associated deaths identified in the clinical trials making it difficult to assess efficacy against this outcome. However, of the COVID-19 associated deaths identified in clinical trials, none have been in study participants receiving COVID-19 vaccines.

Emerging real world evidence from studies in the United Kingdom (UK) [10-12], Israel [13-15][16], the United States (US) [17], and Canada [18][19] suggests moderate to high vaccine effectiveness against severe COVID-19 outcomes after the first or second dose of mRNA COVID-19 vaccines in adults,[10-15, 17, 18][16], and after the first dose of AstraZeneca COVID-19 vaccine [10-12], including in older [10-12, 15] and frail [10] populations. COVID-19 related hospitalization was the most common severe COVID-19 outcome assessed [10-13, 17][16], while fewer studies provided estimates of effectiveness against severe disease [13, 14] and death [11, 13, 18]. Emerging evidence from Israeli

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studies suggest high vaccine effectiveness after the second dose of Pfizer-BioNTech COVID-19 vaccine against severe disease, [13, 14] COVID-19 related hospitalization [13][16] and death [16]. Studies for COVID-19 vaccines are ongoing and new effectiveness data against severe COVID-19 outcomes will be assessed as it emerges.

Efficacy and effectiveness against asymptomatic infection and transmission

Preliminary data from the ongoing Moderna COVID-19 vaccine trial showed a lower prevalence of SARS-CoV-2 positivity by PCR in asymptomatic participants at one particular time point (after Dose one but before Dose 2), and therefore viral shedding, in the group that received the vaccine compared to the placebo group. However, the current data are insufficient to draw conclusions. Exploratory analyses for the AstraZeneca viral vector vaccine have not demonstrated efficacy against confirmed SARS-CoV-2 asymptomatic infection, however the number of asymptomatic infections was small. The clinical trial of the Janssen COVID-19 vaccine found the vaccine to have moderate protection against asymptomatic and undetected COVID-19 infection. Studies are ongoing for these vaccines.

Evidence has begun to emerge from post-marketing studies conducted in Israel, [13] the UK, [20] and the US [21] on the effectiveness of COVID-19 vaccines against asymptomatic infection in adults. Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose [13, 20] (depending on time since vaccination) and high after the second dose [13, 20]. Similar results were reported for mRNA COVID-19 vaccines in general (i.e., Moderna and Pfizer-BioNTech) [21]. In one UK study, asymptomatic SARS-CoV-2 infections were significantly less likely to be identified in vaccinated participants compared to those who were unvaccinated [20]. There are no results specific to other COVID-19 vaccines yet, but studies are ongoing.

Efficacy and effectiveness against variants

Evidence of varying protection and effectiveness offered by authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and viral vector-based COVID-19 vaccines (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine) against variants of SARS-CoV-2 is evolving. Please see Table 5 for a summary of this evidence.

The Janssen clinical trial was conducted during the time of emergence of SARS-CoV-2 VOC. As part of the testing conducted during the trial, a proportion of case isolates were genetically sequenced, and of the sequenced isolates, just over two-thirds of the isolates from Brazil were of the P.2 (Zeta) VOI lineage and nearly all isolates from South Africa were of the B.1.351 (Beta) VOC lineage. Point estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset from 28 days post-vaccine are comparable to the overall estimate of efficacy against this outcome in Brazil and South Africa.

There is evidence that the Pfizer-BioNTech and AstraZeneca vaccines protect against the B.1.1.7 (Alpha) VOC. While there appears to be reduced protection against acquisition of B.1.617.2 (Delta) after the first dose for both Pfizer-BioNTech and AstraZeneca vaccines as compared with other strains, emerging data suggest that Pfizer-BioNTech offers very good protection and the AstraZeneca vaccine offers good protection against infection with the B.1.617.2 (Delta) VOC after the second dose. In addition, the vaccines offer good protection against hospitalization after the first doses. There are also emerging data on the efficacy or effectiveness of mRNA vaccines against B.1.351 (Beta) VOC. Evidence from the Janssen vaccine clinical trials indicate that it is protective against symptomatic moderate to severe/critical COVID-19 infection in areas where B.1.351 (Beta) VOC and P.2 (Zeta) VOI are circulating widely. The AstraZeneca clinical trial was

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conducted when the B.1.351 (Beta) lineage was the predominant strain in South Africa, and vaccine efficacy was not demonstrated against this strain.

NACI will continue to monitor the evidence and update recommendations as needed.

IV.3 Immunogenicity

No immunological correlate of protection has been determined for SARS-CoV-2; therefore, all immunological evidence in support of vaccine efficacy is indirect and cannot directly be used to estimate either vaccine efficacy or effectiveness.

There are several key knowledge gaps that affect the understanding of immune responses to COVID-19 vaccine:

- Which type of immune responses are important for protection from infection, severe disease, or transmission
- What level of humoral and cellular immune responses are necessary to confer protection
- The durability of immune responses and how they may change over time
- How immune responses to natural infection compare to responses elicited from a vaccine
- How immune responses differ across populations (e.g., in immunocompromised persons, children) or by SARS-CoV-2 serostatus (i.e., past COVID-19 infection)
- How immune responses differ based on previous infection with non-SARS-CoV-2 coronaviruses

Due to limitations in the number of participants evaluated for immunogenicity outcomes and duration of follow up from COVID-19 clinical trial data, long-term evidence on immunogenicity is unknown. However, studies are ongoing.

The following section highlights key immunogenicity data for the authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine) and viral vector based COVID-19 vaccines (AstraZeneca COVID-19 vaccine and Janssen COVID-19 vaccine) only. For additional details regarding trial design, including study population and length of follow-up, and immunogenicity for these authorized vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine).

Humoral immune responses

All authorized COVID-19 vaccines induce humoral immune responses, including binding and neutralizing antibody responses. Humoral responses peaked after the second dose of mRNA vaccine, and after the second dose of AstraZeneca COVID-19 vaccine in participants who were not previously infected. Humoral immune responses were elevated after the one dose of Janssen vaccine. Some vaccines induce higher immune responses in younger populations.

Viral vector-based vaccines may induce anti-vector immune responses, which may impact future vaccine efficacy and effectiveness and may vary by age, dose, and interval between doses.

Cellular immune responses

All authorized, available COVID-19 vaccines have been shown to produce cellular immune responses. Cellular immune responses increased after the second dose of mRNA COVID-19 vaccine, while responses for AstraZeneca COVID-19 vaccine were maintained or decreased after

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the second dose. Cellular immune responses were present following one dose of Janssen vaccine.

IV.4 Vaccine Administration

For additional vaccine product-specific information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Vaccine Administration Practices in the Canadian Immunization Guide (CIG), Part 1 - Key Immunization Information for additional general information.

As for the routine administration of all vaccines, COVID-19 vaccines should be administered in settings capable of managing anaphylaxis. Refer to Anaphylaxis and other Acute Reactions Following Vaccination in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

IV.4.1 Dose, route of administration, and schedule

Dose

Pfizer-BioNTech COVID-19 Vaccine

Each dose is 0.3 mL after dilution, containing 30 mcg of SARS-CoV-2 spike protein mRNA.

The dose for the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

Moderna COVID-19 Vaccine

Each dose is 0.5 mL, containing 100 mcg of SARS-CoV-2 spike protein mRNA.

No dilution is required.

AstraZeneca COVID-19 Vaccine

Each dose is 0.5 mL, containing 5×10^{10} particles of SARS-CoV-2 spike protein.

No dilution is required.

Janssen COVID-19 Vaccine

Each dose is 0.5 mL, containing 5×10^{10} particles of SARS-CoV-2 spike protein.

No dilution is required.

Route of administration

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COVID-19 vaccines are given as an intramuscular (IM) injection into the deltoid muscle. The deltoid muscle of the arm is the preferred injection site in adolescents and adults (unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used).

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional general information.

Schedule

Refer to Table 3 for a summary of immunization schedules for authorized, available COVID-19 vaccines.

Table 3. Immunization schedule, by COVID-19 vaccine

Vaccine product	Immunization schedule	Minimum interval	Authorized interval	Extended interval[a]
Pfizer-BioNTech COVID-19 vaccine	2-dose schedule	19 days[b]	21 days	16 weeks
Moderna COVID-19 vaccine	2-dose schedule	21 days[c]	28 days	16 weeks
AstraZeneca COVID-19 vaccine	2-dose schedule	28 days	4 to 12 weeks[d]	16 weeks[d]
Janssen COVID-19 vaccine	1-dose schedule	N/A	N/A	N/A

[a] Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine up to four months after the first. NACI will continue to monitor the evidence and update this interval as needed.
[b] The basis for this minimum interval is that the per-protocol design for the Pfizer-BioNTech COVID-19 vaccine clinical trial was 19-23 days.
[c] The basis for this minimum interval is that the majority of participants in the Moderna COVID-19 vaccine clinical trial received the second dose 21 to 42 days after the first, as per the pre-defined window.
[d] The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.

For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine). Recommendations on extended intervals apply to mixed vaccine schedules.

Refer to Timing of Vaccine Administration in the CIG, Part 1 - Key Immunization Information for additional general information.

Extended intervals for COVID-19 vaccines to optimize early vaccine roll-out and population protection

Currently, no data on medium- or long-term efficacy of COVID-19 vaccines are available. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series, as delays between doses do not result in a reduction

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in final antibody concentrations for most multi-dose (prime-boost) products. For many other multi-dose vaccines provided in adulthood using other vaccine technologies, the greatest proportion of short-term protection is achieved with the first dose with additional doses primarily intended to extend protection over the longer term. However, the follow-up time in COVID-19 vaccine clinical trials is short, the duration of protection after one or both doses is unknown, and mRNA and viral vector-based vaccines represent relatively new vaccine technologies.

Morbidity and mortality from COVID-19 is ongoing. Extending the interval to the second dose of a COVID-19 vaccine maximizes vaccine supply to immunize the largest number of people as quickly as possible. Principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. Please refer to the NACI Advisory Committee Statement: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada in the context of limited vaccine supply (archived) for a summary of the evidence.

Follow-up of vaccine effectiveness in individuals for whom the second dose is delayed or who have otherwise missed their second dose (e.g., missed a follow-up immunization appointment) will be important to inform future recommendations and ensure completion of the vaccine series as soon as possible. NACI will continue to monitor the evidence and update recommendations as needed.

IV.4.2 Booster doses and re-immunization

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete. Given the emergence of VOC against which vaccine effectiveness may be decreased, additional vaccine doses may be necessary. NACI will continue to monitor the evidence and update recommendations as needed.

IV.4.3 Interchangeability

Interchangeability of authorized COVID-19 vaccines in a vaccines series when the first dose is:

mRNA COVID-19 vaccine

NACI recommends that, if readily available*, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available*, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series. The previous dose should be counted, and the series need not be restarted.

(Strong NACI Recommendation)

*readily available = easily available at the time of vaccination without delay or vaccine wastage

AstraZeneca/COVISHIELD COVID-19 vaccine

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NACI recommends that while either an AstraZeneca/COVISHIELD COVID-19 vaccine or an mRNA COVID-19 vaccine product may be offered for the subsequent dose in a vaccine series started with an AstraZeneca/COVISHIELD COVID-19 vaccine, an mRNA COVID-19 product is preferred as a subsequent dose, due to emerging evidence, including the possibility of better immune response, and the safety of heterologous schedules. Regardless of which product is offered, a complete two-dose series is important for protection; the previous dose should be counted, and the series need not be restarted. Individuals who receive two doses of the AstraZeneca/COVISHIELD vaccine are considered protected and do not require further vaccination.

(Discretionary NACI Recommendation)

No data currently exist on the interchangeability of COVID-19 mRNA vaccines. However, there is no reason to believe that mRNA vaccine series completion with a different authorized mRNA vaccine product will result in any additional safety issues or deficiency in protection.

Emerging evidence indicates that mixed COVID-19 viral vector and mRNA vaccine schedules with dosing intervals between 4 and 12 weeks have acceptable safety profiles that may be associated with short-term increased systemic reactogenicity, which is potentially increased with shorter intervals between vaccines. Current evidence indicates that humoral and cellular immune responses (including responses against VOCs) increase when the Pfizer-BioNTech vaccine is administered as the second dose after AstraZeneca vaccine with an interval of 8 to 12 weeks [22], and are equivalent to or greater than immune responses following a homologous two-dose schedule of the AstraZeneca or Pfizer-BioNTech vaccine.

Due to the risk of VITT associated with the second dose of AstraZeneca/COVISHIELD COVID-19 vaccine, offering an alternative product with a more acceptable safety profile and expected comparable immunogenicity profile, while enabling individuals to make an informed choice is ethically justifiable. This is expected to lead to increased accessibility and acceptability for those who were initially offered a first dose of the AstraZeneca/COVISHIELD vaccine, including those who are most at risk of COVID-19. Given the risk of VITT associated with the Janssen vaccine, it should not be offered to individuals who received a first dose of AstraZeneca/COVISHIELD vaccine and prefer to receive an alternative product for their second dose. For more details on VITT, please see Thrombosis with Thrombocytopenia following vaccination with viral vector COVID-19 vaccines.

For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine). Recommendations on extended intervals apply to mixed vaccine schedules. See Table 3 for information on recommended intervals for authorized COVID-19 vaccines.

Recommendations for the interchangeability of COVID-19 vaccines are consistent with the current NACI guidance on interchangeability for vaccines that are used for the same indication and contain comparable antigens. In line with basic principles of vaccinology [23], it is expected that combining different COVID-19 vaccines that induce an immune response against the SARS-CoV-2 spike protein will lead to a robust immune response. All currently authorized COVID-19 vaccines in Canada use the spike protein of the SARS-CoV-2 virus as the antigen. The spike protein produced by the mRNA (Pfizer-BioNTech, Moderna) and Janssen vaccines is stabilized in the

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prefusion conformation while the AstraZeneca vaccine produces a wild-type spike protein in various conformations, including prefusion.

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines have been reported in Canada and internationally, most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose in a two-dose homologous vaccination series compared to the first dose. The majority of cases are mild and individuals recover quickly. For more details on myocarditis/pericarditis, please see Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine.

Active surveillance of effectiveness and safety of a mixed schedule are important, and accurate recording of vaccines received will be critical. NACI will continue to monitor the evidence and update its recommendations as needed. For additional details on evidence related to mixed COVID-19 vaccine schedules, see NACI Rapid response: Interchangeability of authorized COVID-19 vaccines (archived).

IV.4.4 Post-vaccination counseling

NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.

Analgesics and antipyretics were used in clinical trials of COVID-19 vaccine for the management of pain and/or fever after vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.

All vaccine recipients should be instructed to seek medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the immunization clinic/venue.

All vaccine recipients who develop symptoms compatible with COVID-19 should be tested for SARS-CoV-2 to document breakthrough illness, particularly in the context of the emergence of VOC. Genetic sequencing should be strongly considered for those with SARS-CoV-2 infection after vaccination with either one or two doses of a COVID-19 vaccine.

Anyone receiving a viral vector COVID-19 vaccine should be informed of the recently recognized adverse event of thrombosis with thrombocytopenia syndrome and advised to seek immediate medical attention if they develop symptoms within 42 days of vaccination [24]. Symptoms to be vigilant for include: shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision, skin bruising (other than at the site of vaccination) or petechiae. In addition, healthcare professionals should be aware of VITT including how to diagnose and treat the condition (see national guidance from Thrombosis Canada).

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Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional information on pre- and post-vaccination counseling.

IV.5 Serological testing

Serologic testing is not needed before or after immunization with COVID-19 vaccine.

IV.6 Storage requirements

Pfizer-BioNTech COVID-19 vaccine

Frozen vials prior to use
The Pfizer-BioNTech COVID-19 vaccine must be stored at ultra-low temperatures of -80°C to -60°C and protected from light, in the original packaging, until ready to use.

Refer to the re-icing guidelines (available at CVDVaccine.ca) for instructions regarding the use of the manufacturer's original thermal container for temporary storage.

Vials may also be stored at -25°C to -15°C for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

Thawed, unpunctured vials (prior to dilution)
The Pfizer-BioNTech COVID-19 vaccine may be thawed and stored at +2°C to +8°C for up to 1 month or at room temperature (up to +25°C) for no more than 2 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

Do not refreeze thawed vials.

Thawed, punctured vials (after dilution)
The Pfizer-BioNTech COVID-19 vaccine must be stored between +2°C to +25°C and used within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.

Moderna COVID-19 vaccine

Frozen vials prior to use
The Moderna COVID-19 vaccine should be stored at temperatures of -25°C to -15°C and protected from light in the original packaging. Do not store on dry ice or below -40°C.

Thawed, unpunctured vials
If not punctured, the Moderna COVID-19 vaccine can be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 24 hours.

Do not refreeze thawed vials.

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Thawed, punctured vials
The Moderna COVID-19 vaccine can be stored between +2°C to below +25°C but must be discarded after 24 hours from the time of first puncture.

AstraZeneca COVID-19 vaccine

Unopened multidose vial
The AstraZeneca vaccine can be stored between +2°C to +8°C and protected from light in the original packaging. Do not freeze.

Opened multidose vial
After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (up to +30°C) or 48 hours in a refrigerator (+2°C to +8°C).

After the first puncture, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.

Janssen COVID-19 vaccine

Unopened multidose vial
The Janssen COVID-19 vaccine can be stored between +2°C to +8°C and protected from light in the original packaging. Do not freeze.

Punctured multidose vial
After the first dose has been withdrawn, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours, after the first puncturing of the vial. Discard if vaccine is not used within this time.

For more information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

IV.7 Simultaneous administration with other vaccines

NACI recommends that COVID-19 vaccines should not routinely be given simultaneously with other vaccines (live or inactivated). *(Strong NACI Recommendation)*

There are currently no data on the simultaneous administration of COVID-19 vaccine with other vaccines, although a number of studies are ongoing. In the absence of evidence, a precautionary approach is being recommended at this time. The potential for immune interference is not known. In addition, administering the COVID-19 vaccine alone assists with the assessment of any adverse event following immunization (AEFI). However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

In the absence of evidence, it would be prudent to wait for a period of at least 28 days after any dose of a COVID-19 vaccine before the administration of another non-COVID-19 vaccine due to the elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at

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least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine.

The minimum waiting period between vaccines is precautionary and there may be circumstances in which simultaneous administration or a shortened interval may be warranted on an individual basis. These circumstances may include:

- when another vaccine is required for post-exposure prophylaxis;
- when individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant;
- when there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date;
- when it will enable a pregnant person to receive the Tdap vaccine at 32 weeks gestation or earlier; and
- at the clinical discretion of the healthcare provider.

If a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent is provided, a shorter waiting period or simultaneous administration of COVID-19 vaccines with other vaccines (live or inactivated) may be considered.

If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

NACI will continue to monitor the evidence and update recommendations as needed.

Refer to Timing of Vaccine Administration in the CIG, Part 1 – Key Immunization Information for additional general information on simultaneous administration of other vaccines.

IV.8 Vaccine safety and adverse events following immunization (AEFI)

Due to limitations in the number of participants and duration of follow-up from COVID-19 clinical trials, medium- and long-term evidence on vaccine safety is limited. However, post-licensure vaccine pharmacovigilance is ongoing and safety signals around the world are detected and communicated globally. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, studies are ongoing.

The following section highlights key safety and AEFI data for the authorized COVID-19 vaccines. For additional details regarding trial design, including study population and length of follow-up, and safety for the vaccines authorized and available for use in Canada, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine). Refer to Appendix E for a summary of the frequency of AEFI for the different COVID-19 vaccine products.

Refer to Part 2 - Vaccine Safety in the CIG for definitions of AEFIs and additional general information.

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IV.8.1 Very common and common adverse events

Common adverse events are defined as those that occur in 1% to less than 10% of vaccine recipients; very common adverse events occur in 10% or more of vaccine recipients. Please see Appendix E for a summary of adverse events identified in clinical trials of authorized, available COVID-19 vaccines.

Local

Pain at the injection site is very common after administration of the currently authorized COVID-19 vaccines. More than 40% of recipients experienced injection site pain. Redness and swelling are common or very common after administration. Localized axillary swelling and tenderness was a solicited adverse event in the Moderna COVID-19 clinical trial and was very common after administration with that vaccine. Local adverse events are usually mild or moderate and resolve within a few days of vaccination. For the authorized mRNA COVID-19 vaccines, pain at the injection site was slightly more frequent in younger authorized age groups including adolescents 12-15 years of age (Pfizer-BioNTech COVID-19 vaccine) compared to older adults. For AstraZeneca COVID-19 vaccine, local reactions were milder and reported less frequently after the second vaccine dose in all age groups. Similar frequencies of local reactions were reported across age groups after administration of the Janssen vaccine.

Systemic

Fatigue, headache, muscle pain, chills, and joint pain are all either common or very common after the administration of the currently authorized COVID-19 vaccines. Fever was very common after administration of the second dose of the mRNA COVID-19 vaccines and common after any dose of viral vector vaccines. More than a quarter of vaccine recipients experienced headache and/or fatigue after any dose. Systemic adverse events are usually mild or moderate intensity and resolve within a few days of vaccination. For the mRNA COVID-19 vaccines, systemic reactions are more frequent after the second vaccine dose and in younger authorized age groups including adolescents 12-15 years of age (Pfizer-BioNTech COVID-19 vaccine). For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose as compared with the first in all age groups. The frequencies of systemic reactions that were reported after administration of the Janssen vaccine were similar across age groups.

Adverse events following the second dose of COVID-19 in individuals previously infected with SARS-CoV-2

Evidence on the safety of vaccine booster doses is available from observational[25] and clinical studies[26][27][28]. Occurrence of solicited and unsolicited systemic adverse events in individuals with prior SARS-CoV-2 infection was slightly higher compared to the SARS-CoV-2 naïve population, primarily in younger adults. However, there was no observed increase in the frequency of more severe adverse events in this population. Two observational studies included less than 100 patients with persistent symptoms from prior COVID-19 infections (long COVID). In this subgroup, receipt of COVID-19 vaccination with either an mRNA or viral vector vaccine was not associated with a worsening of long COVID symptoms or increased reactogenicity following immunization.

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IV.8.2 Uncommon, rare, and very rare adverse events

Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. The probability of detection of very rare adverse events in clinical trials is low given clinical trial population sizes; therefore, ongoing pharmacovigilance is essential.

To date, the available data does not indicate that vaccination of SARS-CoV-2 naïve individuals with authorized COVID-19 vaccines will elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 (e.g., vaccine-enhanced disease); however, further study is needed.

Lymphadenopathy was a solicited event in the Moderna clinical trials but not in other authorized COVID-19 vaccine trials see Appendix E). It was uncommonly reported after administration of the Pfizer-BioNTech, AstraZeneca and Janssen COVID-19 vaccines.

No other solicited uncommon, rare, or very rare adverse events were reported among vaccinated participants in the clinical trials at this time.

Thrombosis with Thrombocytopenia following vaccination with viral vector COVID-19 vaccines

Very rare cases of serious blood clots (at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis) associated with thrombocytopenia have been reported globally following vaccination with viral vector COVID-19 vaccines. The terminology for this syndrome has been evolving since the safety signal was detected. The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) uses the case definition for Thrombosis with Thrombocytopenia Syndrome (TTS) [29] to detect these rare events in Canada. Cases that test positive for a biomarker, anti-PF4 (antibodies to platelet factor 4-polyanion complexes), represent a subset of TTS events and are being referred to clinically as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) or Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).

International case reports and case series have raised the signal that those cases found to be positive for anti-PF4 could be associated with viral vector vaccines [30][31][32][33][2][34]. Evidence on the association between TTS following vaccination with the viral vector COVID-19 vaccines is evolving; however, multiple international surveillance systems have early data that consistently point towards an association between adenovirus vector COVID-19 vaccines and TTS, including in the US, UK, and Europe. The exact mechanism by which the viral vector COVID-19 vaccines may trigger this syndrome is still under investigation but viral vector vaccines appear to trigger a presentation similar to spontaneous heparin-induced thrombosis (HIT) / autoimmune heparin-induced thrombosis, where antibodies to platelet factor 4 (PF4)-polyanion complexes induce platelet activation, which causes thrombosis and thrombocytopenia [30]. Clots related to VITT can be very aggressive and challenging to treat [35]. Please refer to Thrombosis Canada guidance for clinical management of VITT. They cannot be managed the same way as clots related to oral contraceptives, immobility, or long haul flights, and have an entirely different biologic mechanism of action.

Cases of VITT usually occur between 4 and 28 days after receipt of a viral vector COVID-19 vaccine, and patients should be monitored for symptoms up to 42 days [36]. The rate of VITT is estimated to be between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose of

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AstraZeneca/COVISHIELD COVID-19 vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered. However, as investigations continue, this rate could be as high as 1 in 50,000. For updates to the numbers of cases of TTS and VITT in Canada, please see the "Serious and non-serious adverse events reported" section of Reported side effects following COVID-19 vaccination in Canada. The frequency of TTS following a second dose of AstraZeneca vaccine is currently reported between 1 per 600,000 and 1 per 750,000 individuals vaccinated with a second dose, based on vaccine safety surveillance data from the United Kingdom but this continues to evolve [2]. The case fatality rate of VITT also varies between countries, and ranges between 20 and 50%. Many cases have been reported to have serious long-term morbidity, including neurologic injury. Reports of TTS after administration of the Janssen vaccine are emerging from the United States. As of May 24, 2021, 32 cases have been confirmed after about 10.2 million doses of Janssen vaccine administered in the United States, and others are under investigation. For more information, see Appendix C, Appendix D, and NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.

Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines[37] have been reported in Canada and internationally, including from Israel[38], the United States[39], and Europe [38]. In Israel and the United States, cases of myocarditis and pericarditis have been reported most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose [40, 41]. Data in Canada are emerging and surveillance is ongoing [42].

There are many potential causes for myocarditis and pericarditis including both infectious and non-infectious causes. Disease severity can be variable. The cases of myocarditis and pericarditis that have been reported after vaccination with an mRNA COVID-19 vaccine to date have generally been mild, and individuals tend to recover quickly [43-46]. Symptoms can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. Symptoms can be accompanied by abnormal tests (e.g., electrocardiogram, serum troponins, echocardiogram).

Based on cases reported internationally, available information indicates that cases of myocarditis and pericarditis after vaccination with an mRNA COVID-19 vaccine occur:

- More often after the second dose
- Usually within a week after vaccination
- More often in adolescents and young adults
- More often in males than females.

As part of ongoing COVID-19 vaccine safety efforts, PHAC and Health Canada are closely monitoring myocarditis and pericarditis through passive and active Canadian safety surveillance systems and collaboration with Canadian provincial and territorial health authorities, manufacturers and international regulators.

NACI continues to review information as it becomes available and will take appropriate action as needed.

Refer to the PHAC weekly AEFI report for information on numbers of cases reported in Canada. Refer to Reporting Adverse Events Following Immunization (AEFI) in Canada and to the recently developed Brighton Collaboration case definition of myocarditis for additional information on the completion and submission of AEFI reports.

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Capillary leak syndrome following vaccination with AstraZeneca COVID-19 vaccine

Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine [2, 3, 38]. CLS is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin (an important blood protein). Symptoms are often associated with feeling faint (due to low blood pressure).

In Canada, as of June 18, 2021, one case of CLS had been confirmed [47] among more than 2,250,000 doses of AstraZeneca/COVISHIELD vaccines administered. As of May 27, 2021, six cases of CLS in individuals who had received the AstraZeneca COVID-19 vaccine had been reviewed by the European Medicine Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) among 78 million doses of AstraZeneca COVID-19 vaccine administered in the United Kingdom (UK) and European Economic Area/European Union (EU/EEA). Three of those affected had a previous history of CLS and one subsequently died. Following its review, the EMA's PRAC has concluded that individuals with a history of CLS should not be vaccinated with the AstraZeneca COVID-19 vaccine.

PHAC and Health Canada are closely monitoring CLS in relation to the AstraZeneca vaccine. Health Canada is working closely with the manufacturers to ensure the labelling reflects relevant information [42].

Cases of CLS following COVID-19 vaccination in Canada should be reported to assist with vaccine safety monitoring. Refer to Reporting Adverse Events Following Immunization (AEFI) in Canada for additional information on the completion and submission of AEFI reports.

Please see ***Section IV.10 Contraindications and Precautions*** for additional guidance on CLS as a contraindication for the Astra-Zeneca/COVISHIELD COVID-19 vaccine.

IV.8.3 Guidance on reporting adverse events following immunization (AEFI)

Vaccine providers are asked to report AEFIs through local public health departments and to follow AEFI reporting requirements that are specific to their province or territory. In general, any serious (defined as resulting in hospitalization, permanent disability or death) or unexpected adverse event that is temporally related to vaccination should be reported.

In addition to provincial or territorial reporting requirements, the Brighton Collaboration has developed a list of Adverse Events of Special Interest (AESI) that are of particular interest and should be reported. Refer to https://brightoncollaboration.us/covid-19/ for the list with definitions.

There may be additional very rare AEFIs that have not been detected through clinical trials to date.

Refer to Adverse Events Following Immunization (AEFI) in the CIG, Part 2 – Vaccine Safety for additional information on definitions, reporting, investigating and managing, and causality assessments for AEFIs.

Refer to Reporting Adverse Events Following Immunization (AEFI) in Canada for additional information on the completion and submission of AEFI reports.

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Refer to the PHAC weekly report for reported adverse events following COVID-19 vaccination in Canada.

IV.9 Special Populations

The following populations were either excluded from, or included in small numbers, in clinical trials for the COVID-19 vaccines. However, real-world data from the use of COVID-19 vaccines in these populations is accumulating. NACI will continue to monitor the evidence and update recommendations as needed.

Individuals previously infected with SARS-CoV-2

In studies that reported immune responses in individuals with previous SARS-CoV-2 infection [48][26][49][50][51][52], anti-spike and anti-RBD IgG concentrations, neutralizing titres and B and T cell responses after dose 1 were comparable to those observed in SARS-CoV-2 naïve individuals following the administration of the second vaccine dose. Elevated binding and neutralizing antibody responses were seen for both symptomatic and asymptomatic people who were previously infected compared to vaccine recipients who were not previously infected. These findings were consistent with those reported by the RECOVER [52] study investigators. However, in the absence of an established correlate of protection, it is not possible to determine the significance of these findings as they relate to the level of protection against reinfection.

Individuals who are immunosuppressed due to disease or treatment

Evidence on the safety of COVID-19 vaccination in these individuals is emerging. Safety data in immunocompromised individuals, including those receiving immunosuppressive therapy, were available from observational studies in solid organ transplant recipients, cancer patients and individuals with chronic inflammatory diseases who were taking immunosuppressive therapies [53][54][55][56][57][58][59][60][61][62][63][64][65][66]. The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine in these populations were comparable to that of non-immunosuppressed individuals in these studies and what was reported in clinical trials. Safety data in these populations following vaccination with a viral vector vaccine is not available.

The efficacy and effectiveness of COVID-19 vaccines in immunosuppressed populations is currently unknown, but evidence of a diminished immune response is emerging. Immunogenicity data in immunocompromised individuals, including those receiving immunosuppressive therapy, were available from observational studies in solid organ transplant recipients, cancer patients and individuals with chronic inflammatory diseases who were taking immunosuppressive therapies[67][68][69][60][59][61][70][71][72][73][74][64][75][66][76][77][78][79][80][55][81][57][58,82]. Study participants showed diminished or delayed immune responses to mRNA or AstraZeneca COVID-19 vaccines. The type of immunosuppressive therapy or condition affected the immune response to COVID-19 vaccines, leading to a lack of humoral and cellular responses in some cases or diminished levels in those who did develop responses compared to healthy controls. Given the limited number of participants and the lack of an immunological correlate of protection against SARS-CoV-2 infection, there are limitations in interpreting the significance of these results. The same general principles may apply to those with chronic kidney disease receiving hemodialysis (for whom there is strong evidence of an increased risk of mortality for COVID-19), as individuals with impaired renal function have a less than optimal response to immunization [83][84][64][85][77][76][86][87][88][89][90][91][92][93].

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Individuals who have an autoimmune condition

Emerging safety data from observational studies in individuals with autoimmune conditions indicates that the frequency and severity of adverse events in this population is comparable to that of individuals without autoimmune conditions and what was reported in clinical trials [53][54][55][56][57, 58][94]. The onset of new autoimmune disease or disease exacerbation following vaccination with mRNA COVID-19 vaccines was rare or comparable to the background incidence of these events in the general population. Safety data in this population following vaccination with a viral vector vaccine is not available.

The efficacy and effectiveness of COVID-19 vaccines in individuals with autoimmune conditions is unknown, but immunogenicity data is emerging. Data were available from observational studies in which participants received the mRNA or the AstraZeneca COVID-19 vaccines [80][55][81][57][82][58]. Immune responses were diminished only in participants who were also receiving immunosuppressive therapy. Given the limited number of participants and the lack of an immunological correlate of protection against SARS-CoV-2 infection, there are limitations in interpreting the significance of these results.

Individuals who are pregnant or breastfeeding

Evidence regarding the safety and immunogenicity of COVID-19 vaccines in individuals who are pregnant or breastfeeding are emerging. Pre-clinical studies on the safety of COVID-19 vaccines from animal developmental and reproductive toxicity studies did not identify concerns regarding female reproduction, fetal/embryonal development, or postnatal development following the administration of the Moderna COVID-19 vaccine prior to or during gestation [95]. A report presented to the European Medicines Agency (EMA) also did not indicate adverse effects with respect to fertility, pregnancy, embryo/fetal development, or postnatal development (up to day 21) in studies in rats using a full dose of the Pfizer-BioNTech COVID-19 vaccine [96]. A US Food and Drug Administration (FDA) review of a study in rabbits that received the Janssen COVID-19 vaccine at two times the human dose prior to or during gestation similarly concluded there were no adverse effects on female reproduction, fetal/embryonal development, or postnatal development [97]. AstraZeneca performed a preliminary DART study in 32 female mice given the vaccine prior to or during gestation and found no effects of female reproduction, fetal or pup survival or development. Their main DART study in mice is ongoing [98].

Analysis of data collected through international COVID-19 immunization registries to date have not revealed any maternal or neonatal safety signals, and preliminary analyses of over 35,000 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals [99] In one small cohort study, mRNA from COVID-19 vaccines was undetectable in breastmilk 4-48 hours post-vaccination [100].

Emerging evidence suggests that COVID-19 mRNA vaccination during pregnancy is also immunogenic and results in comparable antibody titres to those generated in non-pregnant women [101][102][103]. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose [104][101][105, 106]. Observational studies consistently show that both anti-spike IgG and IgA are present in breastmilk for at least 6 weeks after maternal vaccination with mRNA vaccines [107][108][109][110].

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IV.10 Contraindications and Precautions

Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines.

Table 4 lists potential non-medicinal ingredients in authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products. These reactions have occurred rarely and ranged from mild cutaneous reactions to anaphylaxis. Anaphylaxis is typically a rare, severe, life-threatening allergic reaction usually with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include, but are not limited to: generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock. It is important to note that other, less serious reactions may mimic allergic reactions (e.g., vasovagal syncope) and vaccination is not contraindicated in these cases.

Refer to https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

Table 4. Ingredients of authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products

Vaccine product	Potential allergen included in the vaccine or its container	Other products where the potential allergen may be found
Pfizer-BioNTech COVID-19 vaccine	polyethylene glycol (PEG) [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel[d].
Moderna COVID-19 vaccine	PEG [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel[d].
	tromethamine[e] (trometamol or Tris)	Component in contrast media, oral and parenteral medications.
AstraZeneca COVID-19 vaccine	polysorbate 80[c]	medical preparations (e.g., vitamin oils, tablets, and anticancer agents), cosmetics[d,f]

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Janssen COVID-19 vaccine	polysorbate 80[c]	medical preparations (e.g., vitamin oils, tablets, and anticancer agents), cosmetics[d,f]

*N.B. This is not a complete list of products.

[a] Medications that contain PEG are described in Stone CA, et al., DOI:10.1016/j.jaip.2018.12.003

[b] A review of immediate type hypersensitivity reactions to PEG is available in Wenande et al, DOI: 10.1111/cea.12760

[c] There is a potential of cross-reactive hypersensitivity between PEG and polysorbates

[d] PEG is an additive in some food and drinks but allergic reactions to PEG in food or drinks have not been documented.

[e] One case report of anaphylaxis to tromethamine has been described (Lukawska et al, DOI: 10.1016/j.jaip.2018.08.035).

[f] Case reports of anaphylaxis to polysorbate 80 have been described (Badiu et al, DOI: 10.1136/bcr.02.2012.5797, Palacios Castaño et al, DOI: 10.18176/jiaci.0109).

Rare cases of VITT have been reported following immunization with viral vector COVID-19 vaccines. Investigations are ongoing and the recommendations will be updated as evidence becomes available. For more information, refer to Appendix C and Appendix D

Contraindications

Anaphylaxis and Allergies to a COVID-19 vaccine

An authorized COVID-19 vaccine should not be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector). If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e., individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine and individuals with anaphylaxis post viral vector vaccine may be offered a mRNA vaccine). If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization.

An authorized COVID-19 vaccine should not be routinely offered to individuals who are allergic to any component of the specific COVID-19 vaccine or its container. For a comprehensive list of components in each authorized COVID-19 vaccine and its container, please consult the corresponding product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.

Thrombosis and Thrombocytopenia following vaccination

Patients who have experienced venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 vaccine.

Capillary leak syndrome

As a precautionary measure following the international cases that have been reported, individuals with a history of capillary leak syndrome should not receive the AstraZeneca /COVISHIELD COVID-19 vaccine.

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Precautions

Hypersensitivity and Allergies

If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided; vaccination may be considered in individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) after a previous dose of authorized COVID-19 vaccines or any of its components. Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if vaccination is chosen, an extended period of observation post-vaccination of at least 30 minutes should be provided for the aforementioned individuals.

Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.

Acute illness

Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from SARS-CoV-2 infection to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any persons are identified with symptoms on arrival at the venue, they should be instructed to follow current local public health measures.

As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, one should wait until all symptoms of an acute illness are resolved before vaccinating with an authorized COVID-19 vaccine.

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Hematologic

In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.

Thrombosis and Thrombocytopenia

Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered.

Anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risk of VITT and advised to seek immediate medical attention if they develop symptoms of VITT. These symptoms may include: shortness of breath, chest pain, leg swelling or pain, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms after vaccination including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizures, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

Myocarditis and/or pericarditis

Post-market safety surveillance on mRNA COVID-19 vaccines has identified an increased frequency of myocarditis and pericarditis internationally, reported very rarely but most frequently in adolescents and young adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose [40, 41]. The association of myocarditis and pericarditis with mRNA vaccination and a mechanism for inflammation remain under investigation.

As a precautionary measure, the second dose in the mRNA COVID-19 vaccination series should be deferred in individuals who experience myocarditis or pericarditis following the first dose of an mRNA COVID-19 vaccine until more information is available. NACI will continue to monitor the evidence and update recommendations as needed.

Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, or palpitations.

Healthcare providers should consider myocarditis and/or pericarditis in their evaluation if the patient presents with clinically compatible symptoms (chest pain, shortness of breath, palpitations) after the second dose of an mRNA COVID-19 vaccine but should be investigated regardless of timing from vaccination to onset. Investigations include electrocardiogram, serum troponins and echocardiogram with frequent abnormal electrocardiogram findings and elevated troponin levels. Consultation with a cardiologist, infectious disease specialist, internal medicine specialist and/or rheumatologist may be advisable to assist in this evaluation, particularly to investigate the many potential causes of myocarditis and pericarditis. Investigations may include diagnostic testing for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection

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(e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and consideration of other potential infectious or non-infectious etiologies including auto-immune conditions.

Refer to Contraindications and Precautions in the CIG, Part 2 - Vaccine Safety for additional general information.

IV.11 Drug Interactions

There have been no drug interactions studies performed to date.

For more information about potential interactions with products containing anti-SARS-CoV-2 antibodies, refer to section IV.11 Blood products, human immunoglobulin and timing of immunization, in this Statement.

Tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)

There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.

In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent in order to avoid missing cases due to potentially false-negative results.

IV.12 Blood Products, Human Immunoglobulin and Timing of Immunization

NACI recommends that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. Therefore, timing of administration and potential interference between these two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines, which could prevent the production of antibodies stimulated by the vaccine.

In the post-exposure setting, expert clinical opinion should be sought on a case-by-case basis when deciding whether anti-SARS-CoV-2 monoclonal antibodies would be appropriate to administer after receipt of COVID-19 vaccine, taking into consideration the risk of exposure and the risk of severe COVID-19 disease in the individual.

To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two

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products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

V. RECOMMENDATIONS

Following the thorough review of available evidence summarized above, as well as the systematic assessment of ethics, equity, feasibility and acceptability considerations with the EEFA Framework [5] as summarized in NACI's Guidance on Key Populations for Early COVID-19 Immunization, NACI makes the following evidence-informed recommendations for public health program level decision-making for the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada.

NACI will continue to carefully monitor the scientific developments related to COVID-19 and COVID-19 vaccines, as well as ongoing vaccine pharmacovigilance, and will update recommendations as required.

Please note:

- A *strong recommendation* applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.
- A *discretionary recommendation* may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

Please see Table 6 for a more detailed explanation of the strength of NACI recommendations.

RECOMMENDATIONS ON AUTHORIZED, AVAILABLE COVID-19 VACCINES

These recommendations apply only to COVID-19 vaccines currently authorized for use in Canada (Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine; AstraZeneca COVID-19 vaccine; and Janssen COVID-19 vaccine). In considering these recommendations and for the purposes of publicly funded program implementation, provinces and territories may consider local programmatic factors (e.g., logistical and operational contexts, resources) and local epidemiology (e.g., transmission of SARS-CoV-2 VOC).

1. **NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine.**
   (Strong NACI Recommendation)

2. **NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, as well as the need to seek immediate medical care should symptoms develop.**
   (Discretionary NACI Recommendation)

Refer to the Table 5 for a summary of evidence and factors for jurisdictions to consider when implementing COVID-19 immunization programs.

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Summary of evidence and rationale:

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption. The COVID-19 immunization program should be rolled out as efficiently, effectively and equitably as possible.
- mRNA COVID-19 vaccines are authorized in individuals 12 years of age and older (Pfizer-BioNTech COVID-19 vaccine) and in individuals 18 years of age and older (Moderna COVID-19 vaccine). Non-replicating viral vector vaccines are authorized for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine).
- A complete series for all currently authorized and available COVID-19 vaccines is two doses except for the Janssen COVID-19 vaccine which is authorized as a single dose.
- See Table 1 for risk factors associated with increased risk of severe outcomes from COVID-19 and increased risk of exposure to COVID-19. Please refer to NACI's Guidance on the prioritization of key populations for COVID-19 immunization for additional details on sequencing of key populations, including a comprehensive analysis of ethical, equity, feasibility and acceptability considerations.

mRNA COVID-19 vaccines

- Clinical trial data available to date have shown that the currently authorized mRNA COVID-19 vaccines are highly efficacious (≥94%) in preventing confirmed symptomatic COVID-19 disease in the short term, starting at one to two weeks after receiving the full two-dose series.
- Highest efficacy and maximum immune response were observed after the second dose. Efficacy of a two-dose series was consistent across age groups.
- Estimates of vaccine effectiveness of the Pfizer-BioNTech vaccine were comparable in countries where the predominant circulating strain was the B.1.1.7 (Alpha) VOC. Emerging evidence suggests the Pfizer-BioNTech vaccine is 33.2% effective after the first dose and 87.9% effective after the second dose against the B.1.617.2 (Delta) VOC.
- Local and systemic adverse events were generally less frequent in older adults (≥56 in the Pfizer-BioNTech clinical trial and ≥65 in the Moderna clinical trial).
- The authorized mRNA vaccines are similarly safe and efficacious in those with one or more comorbidities (e.g., body mass index ≥30 kg/m2, chronic pulmonary disease, diabetes mellitus, cardiac disease).

Informed consent for mRNA COVID-19 vaccines should include information about very rare reports of myocarditis or pericarditis in the week following an mRNA vaccine

- Post-market safety surveillance reports of myocarditis/pericarditis following mRNA vaccines have been reported most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose [40, 41].
- The majority of cases are mild and individuals tend to recover quickly.
- Anyone receiving an mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop symptoms, which include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.

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- As a precautionary measure, the second dose in the mRNA COVID-19 vaccination series should be deferred in individuals who experience myocarditis or pericarditis as an adverse event following the first dose of an mRNA COVID-19 vaccine until more information is available. NACI will continue to monitor the evidence and update recommendations as needed.
- Informed consent should also include discussion about the individual's personal risk of severe COVID-19 disease (see Table 1), risk of infection and local epidemiology (including circulation of VOC), complications of COVID-19 (which may include myocarditis and pericarditis), and protection offered by COVID-19 vaccination.
    - Vaccination for adolescents and young adults is recommended as the benefits of vaccination to prevent COVID-19 including variants of concern, outweigh very rare cases of myocarditits/pericarditis.
    - Individuals aged 12 to 24 years account for approximately 15% of the Canadian population [111], and similarly, this age group constitutes approximately 18% of cumulative COVID-19 cases reported nationally. However, with the increasing number of older adults who have been immunized against COVID-19, the relative proportion of COVID-19 cases has been increasing among younger age groups. In contrast to older populations, this age group accounts for less than 2% of COVID-19 cases resulting in hospitalization, less than 2% of COVID-19 cases admitted to ICU, and less than 0.1% of deaths from COVID-19 [112].
    - Some individuals are at increased risk of hospitalization and mortality from COVID-19 (see Table 1). An updated rapid review of risk factors for severe illness conducted by the Alberta Research Centre for Health Evidence (ARCHE) found a moderate certainty of evidence of ≥2-fold increase in hospitalizations in individuals 21 years of age and younger with 2 or more chronic conditions (versus no chronic conditions) [7].
    - There is emerging evidence that mRNA vaccines offer good protection against infection with the B.1.617.2 (Delta) VOC after the second dose and very good protection against hospitalization after the first dose.
    - In clinical trials, mRNA COVID-19 vaccines have been shown to be immunogenic and efficacious in preventing symptomatic disease in adolescents and young adults. Clinical trials demonstrated a similar safety profile to that observed in older age groups.

AstraZeneca COVID-19 vaccine

- Combined evidence from clinical trial and observational study data available to date have shown that the AstraZeneca COVID-19 vaccine offers protection against symptomatic COVID-19 disease and hospitalization in adults ≥18 years of age after receiving at least one dose.
    - Clinical trial data available to date have shown that the AstraZeneca COVID-19 vaccine has demonstrated moderate efficacy against symptomatic, confirmed COVID-19 of approximately 62% in those 18-64 years of age. Efficacy of a two-dose series increased to approximately 82% when the interval between doses was 12 weeks or more. In adults 65 years of age and over, observational data from the UK of vaccine effectiveness after one dose have shown a reduction in the risk of symptomatic disease and hospitalization.

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  - The highest efficacy with the authorized regimen of AstraZeneca COVID-19 vaccine was seen in clinical trial groups that had a longer interval between doses. Clinical trials suggest that vaccine efficacy increases with extended intervals between the first and second dose of vaccine, with a maximum reduction in risk of symptomatic disease observed at 12 weeks or more following the priming dose.
- Data suggest AstraZeneca COVID-19 vaccine has a vaccine efficacy of 74.6% against the B.1.1.7 (Alpha) VOC (compared to 84.1% against the non-B.1.1.7 (Alpha) strain). Published data suggests a vaccine efficacy of 10.4% against mild to moderate illness from the B.1.351 (Beta) VOC. Emerging data suggest the AstraZeneca vaccine is 32.9% effective after one dose and 59.8% effective after the second dose against the B.1.617.2 (Delta) VOC.
- In clinical trials, the majority of local and systemic adverse events with the AstraZeneca COVID-19 vaccine were mild and transient and did not differ by dose administered or age.
- Very rare but serious cases of blood clots, including cerebral venous sinus thrombosis, with concurrent thrombocytopenia have been reported globally following post-licensure use of viral vector COVID-19 vaccines. The exact mechanism by which these vaccines may trigger thrombosis with thrombocytopenia is still under investigation. The case fatality rate typically ranges between 20 and 50%.
- AstraZeneca COVID-19 vaccine is similarly efficacious in those with one or more mild to moderate and controlled medical conditions (e.g., cardiovascular disease, respiratory disease, diabetes, body mass index $\geq$30 kg/m^2).

Janssen COVID-19 vaccine

- Clinical trial data available to date have shown that the Janssen COVID-19 vaccine is 67% efficacious against moderate to severe/critical symptomatic COVID-19 disease at least two weeks after receiving one dose.
- Efficacy was consistent across age groups.
- Point estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection from 28 days post-vaccination were comparable in the trial conducted in Brazil (68%), where two-thirds of the isolates were of the P.2 (Zeta) lineage and in the one conducted in South Africa (64%), where almost all isolates were of the B.1.351 (Beta) lineage.
- Local and systemic adverse events were typically mild and transient, and no safety signals were detected in clinical trials.
- As of May 24, 2021, 32 TTS cases were confirmed to have tested positive for anti-PF4 antibodies after about 10.2 million doses of Janssen vaccine administered in the United States.
- The vaccine is similarly safe and efficacious in those with one or more comorbidities 14 days after vaccination, although efficacy is somewhat lower in participants with comorbidities at 28 days post-vaccination.

mRNA COVID-19 vaccines versus viral vector COVID-19 vaccines

NACI reviewed the recent epidemiology of COVID-19 in Canada (including circulation of variants), vaccine characteristics (including efficacy, effectiveness, safety), evidence and international guidance on VITT, anticipated vaccine supplies, Health Canada's assessment of COVID-19 vaccines, as well as a comprehensive analysis of the implications on ethics, equity, feasibility and acceptability [5] of its recommendations for the use of COVID-19 vaccines in Canada.

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NACI concluded that the advantages of safe, highly efficacious mRNA COVID-19 vaccines outweigh any possible disadvantages for eligible populations. Therefore, NACI made a strong recommendation for the preferential use of mRNA COVID-19 vaccines in all authorized age groups. NACI cautions that there is uncertainty in the evidence of advantages and disadvantages of the use of viral vector COVID-19 vaccines for eligible populations in Canada due to the risk of a rare but serious adverse event (Vaccine Induced Thrombotic Thrombocytopenia, VITT); the availability of other safe, highly efficacious mRNA COVID-19 vaccines; as well as some evidence of lower protection against asymptomatic transmission and the B.1.351 (Beta) and B.1.617.2 (Delta) VOC with the AstraZeneca vaccine. Therefore, NACI made a discretionary recommendation on the use of viral vector COVID-19 vaccines.

NACI previously made a discretionary recommendation on the use of viral vector COVID-19 vaccines for individuals who prefer an earlier vaccine rather than wait for an mRNA vaccine, only if certain conditions were met (including a benefit-risk analysis, informed consent, and substantial delay for receipt of an mRNA vaccine). This recommendation was based on a public health benefit-risk analysis using rates of VITT reported at that time (this analysis is available in archived versions of this statement). However, with increasing reported rates of VITT following vaccination with viral vector vaccines and increasing mRNA vaccine supplies in Canada, NACI now recommends that viral vector vaccines may be offered only if mRNA vaccines are contraindicated or inaccessible.

A summary of the evidence and rationale for NACI's preferential recommendation for the use of mRNA COVID-19 vaccines in population-level programs and discretionary recommendation for the use of a viral vector COVID-19 vaccine for individuals when other authorized COVID-19 vaccines are contraindicated or inaccessible is below:

- **Epidemiology**: The epidemiology and risk of COVID-19 vary across Canada and between populations. The proportion of COVID-19 cases classified as a VOC is increasing in Canada. Cases classified with a VOC are hospitalized more often relative to those without a VOC in those aged 20 and over. NACI will continue to monitor the evolving epidemiology.
- **Efficacy and Effectiveness**: Emerging data suggest that all authorized vaccines offer protection against hospitalization and likely also death from COVID-19. In clinical trials, mRNA COVID-19 vaccines demonstrated higher efficacy than was shown for the viral vector COVID-19 vaccines. There is evidence that the mRNA COVID-19 vaccines and the AstraZeneca COVID-19 vaccine offer protection against the B.1.1.7 (Alpha) VOC. There is also emerging vaccine effectiveness evidence that suggests the Pfizer-BioNTech vaccine offers very good protection (87.9%) and the AstraZeneca vaccine provides good protection (59.8%) against the B.1.617.2 (Delta) VOC after the second dose. Effectiveness is much lower after only one dose of either the Pfizer-BioNTech and AstraZeneca vaccines (33.2% and 32.9% respectively). The mRNA COVID-19 vaccines and Janssen COVID-19 vaccines seem to offer protection against the B.1.351 (Beta) VOC, but the AstraZeneca COVID-19 vaccine does not. In studies in Brazil, the Janssen vaccine was shown to offer protection against the P2 (Zeta) VOI. There is limited evidence on the protection of mRNA or viral vector COVID-19 vaccines against the P.1 (Gamma) VOC.
- **Safety**:
  - Very rare cases of serious blood clots associated with thrombocytopenia have been reported globally following vaccination with viral vector COVID-19 vaccines. The rate of VITT is estimated to be between 1 per 26,000 and 1 per 100,000 persons vaccinated with a first dose of AstraZeneca/COVISHIELD

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COVID-19 vaccine. As of June 1, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered. However, as investigations continue, this rate could be as high as 1 in 50,000. The case fatality rate of VITT also varies between countries, and ranges between 20 and 50%. Many cases have been reported to have serious long-term morbidity, including neurologic injury. As of May 24, 2021, 32 cases of this adverse event have been confirmed after about 10.2 million doses of Janssen vaccine administered in the United States, and others are under investigation.

- Very rare cases of a serious condition called capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine. Post-market safety surveillance on mRNA COVID-19 vaccines has found an increased frequency of myocarditis and pericarditis following a second dose of a COVID-19 mRNA vaccine and in younger males and adolescents. However the majority of cases reported were mild and individuals tended to recover quickly.

- **Ethics**: NACI consulted with the Public Health Ethics Consultative Group (PHECG) on the ethical considerations for restricting the use of a viral vector vaccine in the current and anticipated pandemic and vaccine supply context. The PHECG provided recommendations in the following areas: promoting well-being and minimizing risk of harm, maintaining trust, respect for persons and fostering autonomy, and promoting justice and equity. NACI integrated these recommendations into its guidance. NACI applied the precautionary principle in making its discretionary recommendation, and took into account the evolving evidence on VITT, the potential for harm, the availability of other effective vaccines without this safety signal, as well as evidence of the effectiveness of alternate infection prevention and control measures.
- **Equity**: NACI examined the implications of various recommendation options on the opportunity for all populations to have a fair opportunity to attain their full health potential [5]. Populations that received a viral vector COVID-19 vaccine when mRNA vaccine supplies were limited had protection against COVID-19 disease earlier than if they had waited for mRNA vaccines to be available. However, these populations may ultimately have lower protection, as a larger proportion of the vaccinated population will remain susceptible. NACI considered the impact of the provision of a less efficacious vaccine with a safety signal of concern to marginalized and disadvantaged populations who have been disproportionately affected by the pandemic, and whose lived experience may have led to distrust of governments. Depending on vaccination strategies, this could potentially exacerbate health inequities if this potential harm is not considered when implementing the vaccine program in populations who experience intersecting risk factors for severe disease and exposure (e.g., racialized populations living in multigenerational housing with over-representation in jobs providing essential services such as food and healthcare). With increased supply of mRNA vaccines, inequities will be reduced if viral vector vaccines are offered only when mRNA vaccines are contraindicated or inaccessible.
- **Feasibility**: NACI considered the impact of its recommendations on the successful implementation of COVID-19 immunization programs in the local setting with available resources [5]. Canada has procured and is expecting enough supply of mRNA vaccines to enable vaccination of currently eligible Canadian population before fall 2021, with enough supply to enable all eligible Canadians to receive their first dose by June 2021. Expected supplies of viral vector COVID-19 vaccines for Canada are minimal in comparison to expected supplies of mRNA vaccines. Therefore, the anticipated waiting time to receive an mRNA vaccine is now reduced but may vary between populations and across jurisdictions. The Janssen vaccine is authorized as a single dose vaccine; however, the duration of protection against COVID-19 is unknown.

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- **Acceptability**: NACI reviewed recent Canadian data to consider the potential impact of its recommendations on intention and behaviours toward COVID-19 vaccination. The desire to be vaccinated continues to rise. However, various populations who have been disproportionately affected by the pandemic are also more hesitant or experience barriers in receiving a COVID-19 vaccine (e.g., racialized populations, migrant or undocumented workers). While public opinion research conducted in March 2021 suggested 44-60% of Canadians had no preference on which vaccine they received, surveys conducted in early April 2021 found that Canadians who are planning to get vaccinated are far more comfortable with the mRNA vaccines (90-92%) than the Janssen (70%) or AstraZeneca (41%) vaccines [113]. A follow up survey conducted in late April 2021 found that while comfort with mRNA vaccines remained high (90-92%), comfort receiving the Janssen vaccine decreased to 54% and was similar to comfort with receiving the AstraZeneca vaccine (52%) [114]. A survey of Canadians conducted in early May 2021 found that among unvaccinated respondents, 65% indicated they had a vaccine preference, with most willing to receive mRNA vaccines (58-82%) compared to viral vector vaccines (7-16%) [115]. Data collected over the course of the pandemic have consistently found that Canadians cite "ensuring the safety of the vaccine" as the main reason for delaying or not getting COVID-19 vaccination. NACI transparently summarized the best available evidence (including knowns and unknowns) to develop its evidence-informed expert guidance and enhance trust and confidence in its recommendations.

3. **NACI recommends that jurisdictions should maximize the number of individuals benefiting from the first dose of a COVID-19 vaccine by extending the second dose of COVID-19 vaccine *up to* four months after the first. With the expansion of COVID-19 vaccine supply in Canada, second doses should be offered as soon as possible, with priority given to those at highest risk of severe illness and death from COVID-19 disease after or concurrent with first doses for all remaining eligible populations. *(Strong NACI Recommendation)***

Summary of evidence and rationale:

- Morbidity and mortality from COVID-19 is ongoing. Extending the interval to the second dose allows vaccination of the largest number of people as quickly as possible, providing more people with direct protection and the possibility of indirect and community protection.
- An extended interval of up to four months allows as many eligible populations as possible to be offered vaccination with one dose. The interval between first and second dose may be shortened based on increasing vaccine supply and should not be extended longer than needed to offer first doses of vaccine to eligible individuals.
- Current evidence suggests very good vaccine efficacy against symptomatic COVID-19 from one dose of COVID-19 vaccines, with good effectiveness shown in observational studies (generally between 60 and 80%, with some lower and higher estimates) against symptomatic disease and/or asymptomatic infection, as well as very good effectiveness against hospitalization (approximately 80%) and death (approximately 85% based on one study from the UK). While two doses of mRNA vaccines have shown excellent efficacy and effectiveness, one dose of mRNA vaccines appear to perform similarly to one or two doses of the AstraZeneca vaccine. However, emerging evidence suggests reduced protection offered by one dose of Pfizer-BioNTech and AstraZeneca vaccines against B.1.617.2 (Delta) VOC.

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- Effectiveness has been documented for up to two months after the first dose of the mRNA vaccines, and the AstraZeneca clinical trial publication modelled one-dose efficacy up to 90 days after vaccination.
- Informed expert opinion based on principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.
- The effectiveness of the extended dose strategy will be monitored on an ongoing basis. If indicated, recommendations will be revised.

This recommendation applies to all two-dose COVID-19 vaccines currently authorized for use and available in Canada.

Please see NACI's Statement on Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada (archived) in the context of limited vaccine supply for a summary of the evidence and further rationale for this recommendation.

4. **NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection.** ***(Discretionary NACI Recommendation)***

Summary of evidence and rationale:

- Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.
- On March 30, NACI reaffirmed its recommendation that those previously infected with SARS-CoV-2 be offered a complete series with a COVID-19 vaccine, after considering evidence from observational studies that reported on the immunogenicity and safety of vaccination in previously infected individuals, safety data from pivotal clinical trials of vaccines approved for use in Canada, as well as presentations from the Canadian National Vaccine Safety Network and the University of Montreal RECOVER study.
- In the absence of one-dose vaccine effectiveness data in previously infected individuals (particularly as it relates to the variants of concern), limited second-dose safety data (i.e. impact of disease severity and the interval since previous infection on reactogenicity), and the potential programmatic challenges associated with the communication and implementation of a one-dose strategy, people with previous SARS-CoV-2 infection should continue to receive a complete vaccine series at the recommended intervals, regardless of the severity of their previous infection.
- Currently, there is a lack of evidence on potential differences in vaccine efficacy between those with and without prior evidence of SARS-CoV-2 infection. In COVID-19 vaccine clinical trials to date, individuals with PCR-confirmed SARS-CoV-2 were excluded and there were only a small number of trial participants with serologic evidence of previous infection (IgG+) who had confirmed symptomatic COVID-19 during the trials, therefore efficacy in this population is uncertain.
- There is currently limited data on potential differences in reactogenicity between those with and without prior evidence of SARS-CoV-2 infection. There is a lack of evidence regarding the impact of the severity of the previous infection and the impact of the interval between a previous infection and timing of the first dose on reactogenicity.
- The immune response to SARS-CoV-2 and variants of concern, including duration of immunity and cross-protection, is not yet well understood. Reinfections with SARS-CoV-2 and variants have been reported and research to establish the severity, frequency, and

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risk factors of reinfection is ongoing. There is limited data suggesting individuals with previous infection may generate a comparable or greater immune response to a single dose of vaccine compared to SARS-CoV-2 naïve individuals after receiving 2 doses.

- In the context of limited supply, to allow for the protection of a larger number of at-risk individuals, vaccination with a COVID-19 vaccine may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first three months following infection. However, if challenging from a feasibility perspective, jurisdictions may elect to disregard prior PCR-confirmed SARS-CoV-2 infection status and vaccinate everyone in a given key population.
- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, and to minimize the risk of transmission of COVID-19 at an immunization venue, NACI recommends that symptoms of an acute illness are completely resolved before vaccinating with COVID-19 vaccine, as well as ensuring that the individual is no longer considered infectious based on current criteria.
- NACI will continue to monitor the evidence regarding vaccination in those previously infected with SARS-CoV-2 and will update recommendations as needed.

The following populations were either excluded from or were represented by small numbers of participants in the original pivotal clinical trials. NACI has updated recommendations for these populations as real-world evidence (mostly with mRNA vaccination) has become available. The recommendations above on the use of mRNA COVID-19 vaccines (Recommendation #1) and the use of viral vector COVID-19 vaccines (Recommendation #2), now also apply to those who are immunosuppressed, have autoimmune conditions, are pregnant or are breastfeeding. Clarifications for informed consent in these recommendations and a summary of the evidence and rationale for the recommendations in these populations is included below.

Immunosuppressed persons

5. **NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (*Strong NACI Recommendation*)**

6. **NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in this population. *(Discretionary NACI Recommendation)***

Summary of evidence and rationale

- Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial. However, real-world evidence (mostly with mRNA vaccination) has become available.

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- The efficacy of COVID-19 vaccines in immunocompromised individuals is currently unknown. **Individuals should continue to follow recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission.** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. **A vaccine series should ideally be completed at least two weeks before initiation of immunosuppressive therapies where possible.**
- No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials.
- Safety data in immunocompromised individuals, including those receiving immunosuppressive therapy, were available from observational studies in solid organ transplant recipients, cancer patients and individuals with chronic inflammatory diseases who were taking immunosuppressive therapies [53][54][55][56][57][58][59][60][61][62][63][64][65][66]. The frequency and severity of adverse events following vaccination with an mRNA COVID-19 vaccine in these populations were comparable to that of non-immunosuppressed individuals in these studies and what was reported in clinical trials. Safety data in these populations following vaccination with a viral vector vaccine is not available.
- Observational studies in solid organ transplant recipients, cancer patients and individuals with chronic inflammatory diseases who are taking immunosuppressive therapies showed diminished or delayed immune responses to mRNA or AstraZeneca vaccines [67][68][69][59][60][61][70][71][72][73][74][64][75][66][76][77][78][79][80][55][81][57][82][58]. There is limited evidence that immune responses improve after a second dose of vaccine and the degree of improvement varies according to the type of immunosuppressive therapy or condition [58][77][74][71][80][73][61][79]. Given the limited number of participants and the lack of an immunological correlate of protection against SARS-CoV-2 infection, there are limitations in interpreting the significance of these observational studies.
- In general, non-replicating vaccines may be administered to immunocompromised people. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to the authorized COVID-19 vaccines.
- People living with HIV who are considered immunocompetent should be vaccinated. In observational studies and clinical trials, humoral and cellular immune responses were similar between fully vaccinated people living with HIV and those who were HIV-negative [116][117][118].
- The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function.
- Currently, there is limited evidence about immunodeficiency or immunosuppression as an independent risk factor for severe COVID-19, though evidence is evolving. A rapid review of evidence from OECD member countries found a moderate certainty of evidence for little-to-no association with mortality due to COVID-19 in those with unspecified immunosuppression and little-to-no increase in hospitalization due to COVID-19 with malignancy [7]. The review found a low certainty of evidence for at least a two-fold increase in mortality due to COVID-19 for those with sickle cell disease or severe immunodeficiency; metastatic cancer (in people <70 years); chemotherapy in the past 12 months or radiotherapy in the past 6 months; solid organ, bone marrow, or stem cell transplant. Caution should be taken when interpreting low certainty evidence. There was also low certainty evidence for at least a two-fold increase in hospitalization due to COVID-19 in transplants of any type. However, the review found a moderate certainty of evidence

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of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found [7][9].

- Recent Canadian surveillance data indicates that compared to the general population, a higher proportion of the immunocompromised population or those with malignancy are hospitalized or admitted to the ICU due to COVID-19.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization of Immunocompromised Persons in the CIG, Part 3 – Vaccination of Specific Populations for definitions and additional general information.

Persons with an autoimmune condition

7. **NACI preferentially recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition. Informed consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (*Strong NACI Recommendation*)**

8. **NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group with an autoimmune condition to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in this population.**
(Discretionary NACI Recommendation)

Summary of evidence and rationale

- Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions. However, real-world evidence (mostly with mRNA vaccination) has become available.
- Other applications of mRNA technologies have been for the treatment of cancer, which requires an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk; however, further evaluation is needed. The theoretical concern is similar for viral vector vaccines. However, evidence on the safety of COVID-19 vaccination in individuals with an autoimmune condition is emerging.
- Observational studies in individuals with autoimmune conditions indicates that the frequency and severity of adverse events in this population is comparable to that of individuals without autoimmune conditions and what was reported in clinical trials [53][54][55][56][57][58][94]. The onset of new autoimmune disease or disease exacerbation following vaccination with mRNA COVID-19 vaccines was rare or comparable to the background incidence of these events in the general population. Safety data in these populations following vaccination with a viral vector vaccine is not available.

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- Observational studies in individuals with autoimmune conditions who were taking immunosuppressive therapies showed diminished or delayed immune responses to the mRNA or AstraZeneca vaccines. Given the limited number of participants and the lack of an immunological correlate of protection against SARS-CoV-2 infection, there are limitations in interpreting the significance of these observational studies [80][55][81][57][82][58].
- The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease, and use of medications that impact immune function.
- The evidence about autoimmune conditions as an independent risk factor for severe COVID-19 is evolving. A rapid review of evidence from OECD member countries found strong evidence (of moderate certainty) for at least a 2-fold increase in mortality from COVID-19 with type 1 diabetes, as well as with a group of neurological disorders including multiple sclerosis and myasthenia gravis. The review also found low certainty evidence for a large increase in hospitalization with vasculitis [7]. The review found a moderate certainty of evidence of little or no association with mortality or hospitalization from COVID-19 in those with rheumatoid arthritis, rheumatic or connective tissue disease, or systemic lupus erythematosus [7]. Caution should be taken when interpreting low certainty evidence. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found [7][9].
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Persons with Chronic Diseases in the CIG, Part 3 – Vaccination of Specific Populations for additional general information on autoimmune conditions.

Pregnancy and Breastfeeding

9. NACI preferentially recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. Informed consent should include discussion about emerging evidence on the safety of mRNA COVID-19 vaccines in these populations. (*Strong NACI Recommendation*)

10. NACI recommends that a viral vector COVID-19 vaccine may be offered to individuals in the authorized age group who are pregnant or breastfeeding to initiate a series when other authorized COVID-19 vaccines are contraindicated or inaccessible. Informed consent should include discussion about the risk and symptoms of VITT, the need to seek immediate medical care should symptoms develop, as well as the limited evidence on the use of viral vector COVID-19 vaccines in these populations. (*Discretionary NACI Recommendation*)

Summary of evidence and rationale

- Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 clinical trials. However, outcomes in participants who became pregnant during the clinical trials and fetal outcomes are reported through registries, and real-world evidence (mostly with mRNA vaccination) has become available.

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- An mRNA vaccine is preferred due to published safety data. Recently published preliminary analyses of 35,691 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals [99]. If VITT were to occur after receipt of a viral vector vaccine in a pregnant person, there might be complexity in the medical care. The US safety data suggests mRNA vaccine administration within 30 days of conception is safe [99]. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination with an mRNA vaccine.
- Analysis of data collected through international COVID-19 immunization registries to date have not revealed any maternal or neonatal safety signals.
- To date, no safety signals have been detected in Development and Reproductive Toxicity (DART) animal studies for Pfizer[96], Moderna[95], Janssen[119], and AstraZeneca vaccines[98].
- Emerging evidence suggests that COVID-19 mRNA vaccination during pregnancy results in comparable antibody titres to those generated in non-pregnant women [101] [102] [103]. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose [104] [101] [105] [106].
- Observational studies consistently show that both anti-spike IgG and IgA are present in breastmilk at least for 6 weeks after maternal vaccination with mRNA vaccines [107][108][109][110][120][121][100][122].
- In one small cohort study, mRNA from COVID-19 vaccines was undetectable in breastmilk 4-48 hours post-vaccination. No safety signals have been detected with mRNA vaccination during breastfeeding and individuals should continue to breastfeed after vaccination [10].
- The evidence of pregnancy as an independent risk factor for severe COVID-19 is evolving. A rapid review of evidence from Organisation for Economic Co-operation and Development (OECD) member countries found a low certainty of evidence of at least a two-fold increase in hospitalization due to COVID-19 for pregnancy (any stage) and a low certainty of evidence for little to no increase in mortality. Caution should be taken when interpreting low certainty evidence. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found [7, 9].
- Compared to non-pregnant persons, SARS-CoV-2 infection in pregnancy may increase the risk of complications requiring hospitalization and intensive care, premature birth and caesarean delivery. A review of 438,548 pregnant individuals found pregnancy is a risk factor for poorer pregnancy outcomes, such as preedampsia, pre-term birth, and stillbirth, and that these risks are much greater with severe infection [123]. Canadian-based surveillance of COVID-19 in pregnancy in five provinces from March 1st-December 21st, 2020 with a sample of 1880 pregnant positive cases, saw an increased risk of being hospitalized (RR=5.33, 95% CI: 4.51-6.20) and an increased risk of being admitted to the ICU (RR=5.88, 95% CI: 3.80 to 8.22) compared to non-pregnant counterparts [124]. Ventilatory support in pregnancy is more challenging and the risks are greater to both mother and child.
- Vaccine recipients and health care providers are encouraged to enroll patients who have received a COVID-19 vaccine during pregnancy in COVID-19 vaccine pregnancy registries (refer to Appendix F for a list of COVID-19 vaccine pregnancy registries). Timely reporting on adverse events following immunization to the local public health authority, as

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well as to the vaccine manufacturer, for follow up in these vaccine recipients is strongly encouraged.
- NACI encourages research on COVID-19 vaccination in pregnancy and during breastfeeding.
- NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Pregnancy and Breastfeeding, Part 3 – Vaccination of Specific Populations of the CIG for additional general information.

Children and Adolescents

11. NACI recommends that a complete series with a Pfizer-BioNTech COVID-19 vaccine should be offered to individuals 12 to 15 years of age without contraindications to the vaccine. Informed consent should include discussion about very rare reports of myocarditis and/or pericarditis in the week following an mRNA vaccine dose. *(Strong NACI Recommendation)*

Internationally, cases of myocarditis and/or pericarditis following vaccination with mRNA vaccines have been reported most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose.

Refer to NACI recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12 to 18 years of age.

Summary of evidence and rationale

- Adolescents 12 to 15 years of age and younger represent 4% of the Canadian population and constitute less than 4% of COVID-19 cases reported in Canada up to June 8, 2021. Adolescents account for less than 0.5% of COVID-19 associated hospitalizations, less than 0.5% of COVID-19 cases admitted to ICU, and less than 0.01% of deaths from COVID-19.
- However, there have been recent reports of COVID-19 outbreaks affecting children, specifically related to the B.1.617.2 (Delta) variant, in areas of relatively high rates of vaccination in the adult population. Evidence on whether specific SARS-CoV-2 variants of concern, such as the B.1.617.2 (Delta) variant, may be more infectious due to increased transmissibility or reduced indirect protection conferred by mRNA vaccination of adults is still emerging.
- In Canada, the majority of individuals 17 years of age and younger hospitalized or admitted to intensive care for COVID-19 had one or more underlying health conditions, most frequently asthma, immunodeficiency disease, and cancer [125].
- Evidence from a pivotal clinical trial of the Pfizer-BioNTech COVID-19 vaccine in adolescents 12-15 years of age has demonstrated a safety, immunogenicity and efficacy profile similar to that previously reported in individuals 16 to 25 years of age and older [126].
- Post-market safety surveillance of mRNA COVID-19 vaccines has found an increased frequency of myocarditis and pericarditis most frequently in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose. However the majority of cases have been mild and have resolved.

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Please see ***Informed consent for mRNA COVID-19 vaccines should include information about very rare reports of myocarditis or pericarditis in the week following an mRNA vaccine*** for additional guidance.

- Active surveillance in adolescent vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.
- Evidence on COVID-19 vaccination in those less than 12 years of age is not available at this time. NACI is monitoring the evidence and will update recommendations when results become available.

NACI continues to recommend the following:

- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.

- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded/remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions.

- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, seniors living in congregate care settings, children and adolescents) is recommended. Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.

NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization:

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.

- Jurisdictions should ensure close and rapid monitoring of safety, effectiveness, and coverage of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.

- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

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V.I SUMMARY OF CONSIDERATIONS FOR COVID-19 VACCINES AUTHORIZED FOR USE IN CANADA

There are currently four authorized COVID-19 vaccines in Canada for the prevention of symptomatic COVID-19 that use two different vaccine platforms. The merits of both vaccine platforms have been summarized in Table 5 below. Caution should be taken when comparing vaccines due to differences in studies conducted for each vaccine (e.g., different endpoints, different analyses, different time periods/countries and circulating strains).

Table 5. Vaccination considerations for types of COVID-19 vaccines authorized for use in Canada

Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
Efficacy and Effectiveness	**Efficacy against symptomatic illness after a complete series** • Pfizer-BioNTech vaccine is overall 94% efficacious ≥14 days after dose 2 in study participants 16 years of age and older. Data suggest the Pfizer/BioNTech vaccine is 95% efficacious in participants ≥65 years of age, and 100% efficacious in participants 12-15 years of age, 7 or more days after dose 2. • Moderna vaccine is overall 94% efficacious in participants 18 years of age and older ≥14 days after dose 2. • Data suggest the Moderna vaccine is 86% efficacious in individuals ≥65 years of age ≥14 days after dose 2. **Effectiveness against severe disease, hospitalization and death from mRNA vaccines (with more data available for Pfizer-BioNTech than Moderna)** • Current data from real-world studies indicate that mRNA COVID-19 vaccines provide very good protection against COVID-19 hospitalization in adults following response to the first dose, including in older populations (≥65 years). • Data from real-world studies in adults provide some evidence that mRNA COVID-19 vaccines provide very good protection against COVID-19-related death following response to the first dose. • Real-world studies in adults indicate that mRNA COVID-19 vaccines provide excellent protection against severe disease,	**Efficacy against symptomatic illness after a complete series** • AstraZeneca SD/SD vaccine is 62% efficacious in participants 18 to 64 years of age. • Current data from clinical trials are insufficient to determine the efficacy of the AstraZeneca vaccine in individuals ≥65 years of age. • The interval between the first and second dose of the AstraZeneca vaccine may impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. • The Janssen COVID-19 vaccine (1 dose) is 66.9% and 66.1% efficacious against confirmed symptomatic moderate to severe/critical COVID-19 infection at ≥14 days and ≥28 days post-vaccination, respectively. • The Janssen COVID-19 vaccine is 76.7% and 85.4% efficacious against confirmed symptomatic severe/critical COVID-19 infection at ≥14 days and ≥28 days post-vaccination, respectively. **Effectiveness against symptomatic illness and hospitalization** • Observational data in individuals ≥65 years of age have shown a reduction in the risk of symptomatic disease and hospitalization with one dose of AstraZeneca vaccine.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	including COVID-19 related hospitalization and death following response to the second dose. • Effectiveness data in adolescents 12 to 15 years of age (Pfizer-BioNTech COVID-19 Vaccine) or the Moderna COVID-19 vaccine alone is not currently available.	• Real-world effectiveness data on the Janssen COVID-19 vaccine indicate good protection against SARS-CoV-2 infection [127].
	Efficacy against asymptomatic infection • A preliminary analysis of limited data in an ongoing trial suggests the Moderna COVID-19 vaccine may be efficacious in preventing asymptomatic infection, however data is still being collected and the final analysis is not complete. **Effectiveness against asymptomatic infection** • Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose (depending on time since vaccination) and high after the second dose [9, 16] in adults. Similar results were reported for mRNA COVID-19 vaccines in general [21].	**Efficacy against asymptomatic infection** • An exploratory ad hoc analysis of limited data suggests the AstraZeneca vaccine may not be efficacious in preventing asymptomatic infection. • Preliminary analyses of limited data suggests that the Janssen COVID-19 vaccine has an estimated efficacy of 59.7% against asymptomatic or undetected SARS-CoV-2 infection with onset ≥28 days post-vaccination.
	Re-vaccination • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern. • Re-vaccinating those who initially received an mRNA vaccine with the same or another mRNA vaccine is currently being investigated. • The efficacy and safety of re-vaccinating those who initially received mRNA vaccine with a different COVID-19 vaccine are unknown at this time but are being investigated.	**Re-vaccination** • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern • Re-vaccination with a booster dose of viral vector vaccines may reduce vaccine effectiveness due to the possible development of immunity to the viral vector which may interfere with the immune response to subsequent doses. However, this is still being investigated. • The efficacy and safety of re-vaccinating those who initially received a viral vector vaccine with a different COVID-19 vaccine are unknown at this time.
	Humoral response	**Humoral response**

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
Immunogenicity	• Humoral responses for both mRNA COVID-19 vaccines in clinical trials peaked after a second dose, including elicitation of neutralizing antibodies. However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with protection. • Humoral responses in clinical trials had similar trends in individuals 18 to 55 years of age and individuals 65 to 85 years of age. • Humoral responses for the Pfizer-BioNTech vaccine in adolescents 12 to 15 years of age met and surpassed levels observed in young adults 16 to 25 years of age. • In observational studies, humoral responses in seropositive vaccine recipients after the first dose were comparable to those observed in SARS-COV-2 naïve individuals following administration of the second dose. However, as a correlate of protection is not known, the significance of these findings as they relate to the level of protection against reinfection is unknown [48][26][49, 50][51][52].	• For the AstraZeneca vaccine, humoral responses in clinical trials peaked after a second dose, including elicitation of neutralizing antibodies, for seronegative vaccine recipients. For seropositive vaccine recipients, humoral responses peaked at the first dose and maintained or decreased at the second dose. • For the AstraZeneca vaccine, humoral responses in clinical trials were lower in individuals ≥65 years of age and older, compared to individuals 18 to 64 years of age in unpublished data presented to NACI. Conflicting results have been shown for other age groups in recently published data [128]. • For the Janssen vaccine, humoral responses in clinical trials, including binding antibodies, neutralizing antibodies and antibodies with Fc effector functions, were seen by day 29 after one dose. • For the Janssen vaccine, somewhat lower humoral immune responses were seen in older age cohorts (>65) compared to younger cohorts (18 to 55) in clinical trials. • However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with vaccine protection.
	Cellular response • Both mRNA vaccines have been shown to produce a cellular immune response by one to two weeks after administration of a second dose. • Increases in cellular immune responses response were seen in both younger and older adults. No data exists on cellular immune responses in adolescents 12-15 years of age. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.	**Cellular response** • The AstraZeneca vaccine has been shown to produce cellular immune responses that did not appear to increase after the second dose. • Cellular immune responses do not appear to differ between age groups. • For the Janssen vaccine, cellular immune responses were elicited after one dose of vaccine. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
Protection against variants, including Variants of concern	**B.1.1.7 (Alpha)** • Data suggest comparable vaccine effectiveness of mRNA COVID-19 vaccines against symptomatic and severe illness due to the B.1.1.7 (Alpha) VOC. **B.1.351 (Beta)** • Emerging data suggest that mRNA COVID-19 vaccines are 43% effective against symptomatic illness due to the B.1.351 (Beta) VOC after one dose, and 88% effective after two doses [19]. **P.1 (Gamma) and P.2 (Zeta)** • There are limited data on the efficacy or effectiveness of mRNA vaccines against the P.1 (Gamma) VOC and P.2 (Zeta) VOI. **B.1.617.2 (Delta)** • Emerging data suggest the Pfizer-BioNTech vaccine is 33.2% effective against symptomatic illness due to B.1.617.2 (Delta) after one dose, and 87.9% effective after two doses [129]. • Against any infection (symptomatic or asymptomatic) due to B.1.617.2 (Delta) emerging data suggest the Pfizer-BioNTech vaccine is 30% effective after one dose, and 79% effective after two doses [130]. • Emerging data suggests the Pfizer-BioNTech vaccine is 94% effective against hospitalization due to B.1.617.2 (Delta) after one dose, and 96% effective after two doses [131].	**B.1.1.7 (Alpha)** • Data suggest AstraZeneca COVID-19 vaccine has a vaccine efficacy of 70.4% against the B.1.1.7 (Alpha) VOC first identified in the UK, compared to 81.5% against non-B.1.1.7 strains (where cases were predominantly due to B.1.177, a non-VOI/VOC strain). [132] **B.1.351 (Beta)** • Data suggest AstraZeneca **vaccine** has a vaccine efficacy of 10.4% against the B.1.351 (Beta) VOC against mild to moderate illness [133]. • In South Africa, where the B.1.351 (Beta) VOC was the dominant strain (approximately 95% of preliminary sequenced samples), the Janssen vaccine was 64% efficacious against moderate to severe/critical COVID-19 as of Day 29. **P.1 (Gamma) and P.2 (Zeta)** • There are limited data on the efficacy or effectiveness of viral vector vaccines against the P.1 (Gamma) VOC. • In Brazil, where P.2 (Zeta) was detected in approximately 70% of sequenced samples of COVID-19 cases, the Janssen vaccine was 68% efficacious against moderate to severe/critical COVID-19 as of Day 29. **B.1.617.2 (Delta)** • Emerging data suggest the AstraZeneca vaccine is 32.9% effective against symptomatic illness due to B.1.617.2 (Delta) after one dose, and 59.8% effective after two doses [129]. • Against any infection (symptomatic or asymptomatic) due to B.1.617.2 (Delta) emerging data suggest the AstraZeneca vaccine is 18% effective after one dose, and 60% effective after two doses [130].

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
		• Emerging data suggests the AstraZeneca vaccine is 71% effective against hospitalization due to B.1.617.2 (Delta) after one dose, and 92% effective after two doses [131].
Safety	**Technology** • mRNA vaccines use a new technology (which has been studied in experimental vaccines); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.	**Technology** • Viral vector vaccines use a relatively new technology (the authorized Ebola vaccine uses this technology); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.
	Safety Signals • Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines. • For both vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events, including fever, are more frequent after the second dose. • For the Pfizer-BioNTech COVID-19 vaccine, compared to individuals 16 to 55 years of age, adolescents 12 to 15 years of age demonstrated increased frequency of headache, chills, and fever. Up to 65% of adolescent participants had headaches, up to 42% of adolescent participants had chills, and up to 20% of adolescent participants had fever. Lymphadenopathy in adolescents occurred in 0.8% of vaccine recipients, (0.6% had vaccination-related lymphadenopathy), and no serious adverse events related to the vaccine and no deaths were reported. • Cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines, have been reported in Canada and internationally. In Canada, we are not currently	**Safety Signals** • For both vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events are less frequent after the second dose. • For the AstraZeneca vaccine, rare cases of thrombosis and thrombocytopenia have been reported during post-licensure use. The mechanism of action appears to be similar to spontaneous heparin-induced thrombocytopenia (called VITT-Vaccine-Induced Immune Thrombotic Thrombocytopenia). Internationally, the rate of this adverse event is still to be confirmed but had been most commonly estimated to be between 1/26,000 and 1/100,000 people vaccinated with AstraZeneca vaccine. Based on available evidence as of June 1, 2021, PHAC has estimated the rate of VITT in Canada as 1 in 73,000 doses administered. However, as investigations continue, this rate could be as high as 1 in 50,000 The case fatality rate typically ranges between 20 and 50%. Other predisposing factors for VITT are unclear. • For the Janssen vaccine, in the clinical trial, one case of cerebral venous thrombosis was reported among 21,895 vaccine recipients. As of May 24, 2021, 32 cases of TTS have been

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	seeing higher rates than would be expected in the general population; however, the number of second doses administered to younger ages is small to-date. The evidence on this phenomenon is evolving and investigations into the association between myocarditis/ pericarditis and mRNA vaccines continue in Canada and abroad. Based on cases reported internationally, available information indicates that they occur more often after the second dose, usually within a week after vaccination, more often in young adults and adolescents. Cases that have been reported after receipt of COVID-19 mRNA vaccines have been generally mild and resolved well with medical treatment.	confirmed out of about 10.2 million doses of Janssen vaccine administered in the United States. Investigations are ongoing. • Very rare cases of capillary leak syndrome (CLS) have been reported following immunization with the AstraZeneca COVID-19 vaccine. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia. Individuals with a history of CLS should not receive the AstraZeneca/COVISHIELD COVID-19 vaccine.
Ethics and Equity	• mRNA vaccines have high short-term efficacy in all authorized age groups and Canada anticipates having enough doses of mRNA vaccines for every individual in Canada in 2021. • Vaccines that are more efficacious may be directed to those who are most at risk of severe disease and exposure to limit the exacerbation of existing inequities. • The impact of not offering a less efficacious vaccine earlier to populations who would otherwise have to wait to receive an mRNA vaccine in areas with a high risk of transmission and infection, should take into consideration trust, justice, and the risk of doing harm vs. good.	• Offering any COVID-19 vaccine to those who would otherwise have to wait to receive one could enhance equity. • If protection against COVID-19 disease cannot be boosted for those that received a lower efficacy vaccine first, significant inequities could be created for those who receive a viral vector vaccine compared to an mRNA vaccine, depending on which population groups received the viral vector vaccine. • The viral vector vaccines may offer an option for individuals who are allergic to mRNA vaccine ingredients or their containers. The impact of offering a less efficacious vaccine earlier to some populations should take into consideration trust, justice and the risk of doing harm vs. good.
Feasibility	**Vaccine schedule** • Both mRNA vaccines are given as a two-dose series. • The mRNA vaccines have an authorized schedule of 21 (for the Pfizer vaccine) or 28 days (for the Moderna vaccine) between dose one and dose two. Although NACI currently recommends up to a 4 month extended interval between first and second doses of COVID-19 vaccines for all authorized age groups to maximize the number of individuals benefitting from	**Vaccine schedule** • The AstraZeneca vaccine is given as a two-dose series. The interval between the first and second dose of the AstraZeneca vaccine seems to impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. Although NACI currently recommends up to a 4 month extended interval between first and second doses of COVID-19 vaccines for all authorized age groups to maximize the number of individuals

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	the first dose, current supplies of COVID-19 vaccines now support shorter intervals between doses.	benefitting from the first dose, current supplies of COVID-19 vaccines now support shorter intervals between doses. • The Janssen vaccine is authorized as a single dose. This may increase the feasibility of the completion of a vaccine series. • Vaccine recipients need to be advised of the VITT safety signal and the symptoms to watch for after vaccination.
	Storage requirements • The mRNA vaccines have more challenging transport and storage requirements, requiring frozen or ultra-frozen cold chains. Significant efforts have been undertaken to address these logistical complexities. The storage requirements for these vaccines increase the logistical complexity of offering these vaccines in some venues to increase access for various populations.	**Storage requirements** • The viral vector vaccines are easier to transport, store and handle than mRNA vaccines, and as a result, could be easier to use for wider distribution via pharmacies and primary healthcare providers. • The viral vector vaccines require storage and transport at +2 to +8°C, which uses standard cold chain infrastructure widely available in provinces and territories. • The storage requirements for these vaccines could increase access to the vaccine for various populations.
Acceptability	• It is possible that individuals will favor mRNA vaccines since they have higher proven efficacy. • Fewer cases of COVID-19 are expected after vaccination with a vaccine with high efficacy. The relatively low incidence of cases post-vaccination could positively affect acceptability of COVID-19 vaccines and vaccines in general.	• It is possible that individuals will favor the viral vector vaccines if it offers an earlier opportunity to receive a COVID-19 vaccine and is more convenient to access if they are available at more convenient locations due to ease of transport, storage and handling. • A greater number of COVID-19 cases are expected after vaccination with a vaccine that has lower efficacy. The relatively higher incidence of cases post-vaccination could negatively affect the public's acceptability of COVID-19 vaccines and vaccines in general. • The Janssen vaccine is given as a single dose. This may increase acceptability of vaccination. • Recent cases of VITT detected after administration with the viral vector vaccines have impacted their acceptability.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**

	Concerns about vaccine safety and effectiveness are the two most cited reasons for vaccine refusal [134]
	• In a survey of Canadians conducted between February 9 and 16, 2021 [135], the following results were reported:
	  ○ Of those who indicated they have not yet been vaccinated (n=1954), more respondents 'Agreed' or 'Strongly Agreed' with items stating intention to get a 'safe vaccine' (69%) and an 'effective vaccine' (67%) since Wave 4 of the survey (late May-early June 2020).
	  ○ When respondents who were willing or neutral towards getting vaccinated were asked what is most important with respect to selecting a COVID-19 vaccine to receive (n=1595), 46% selected "Receiving the most effective vaccine", 15% selected "Receiving any vaccine as soon as possible" and 12% selected "Receiving the vaccine with the fewest reported side effects". The number of doses and type of vaccine technology were not important factors, and 14% of respondents indicated they have no preference on what COVID-19 vaccine they receive.
	  ○ For those who will wait to get the vaccine once it is available: 80% will wait to ensure the safety of the vaccine, 64% will wait to ensure the effectiveness of the vaccine (n=691) [136]
	• In a survey of health care providers conducted on Dec 4-13, 2020 [137], the most important factors reported to influence the decision to receive vaccine were vaccine safety (95.5%), followed by vaccine effectiveness (86.7%) (n=14,336)	

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VI. RESEARCH PRIORITIES

COVID-19 disease and associated vaccines are novel; therefore, research is warranted in many areas. Research to address the following outstanding questions (not ordered in terms of importance) is encouraged, drawing from both short-term and long-term data, where available:

New and Emerging Research Priorities

Efficacy, Effectiveness, Immunogenicity and Safety

1. What is the population effectiveness (against infection/transmission, hospitalization and death) and medium and long-term durability of protection of a single dose or a complete series of each COVID-19 vaccine approved in Canada?

2. What is the efficacy, effectiveness, immunogenicity, and safety of COVID-19 vaccines across diverse population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children/adolescents, frailty)? Is a third booster dose of vaccine or a higher dose of vaccine needed to elicit an appropriate immune response in these individuals?

3. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines in individuals who have had a previous laboratory evidence of SARS-CoV-2 infection?
    a. Is there a discernable difference between seronegative and seropositive people in any of the above parameters?
    b. Does previous exposure to SARS-COV-2 impact efficacy, effectiveness, immunogenicity or safety of COVID-19 vaccines?
    c. Can a single-dose vaccine series be as effective and safe in individuals with previously proven COVID-19 disease?
    d. Are there any emerging safety signals with COVID-19 immunization that are not predicted by the current understanding of the safety profile of similar vaccines?
    e. Does vaccination following prior SARS-CoV-2 infection or vaccination of SARS-CoV-2 naïve individuals elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 or other endemic coronaviruses?

4. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines (including potential boosters) against SARS-CoV-2 VOC?

5. What is the correlate of protection for SARS-CoV-2? How are immune responses induced by natural infection similar or different from those induced by vaccines against COVID-19? Is SARS-CoV-2 natural infection (symptomatic or asymptomatic) associated with protection against re-infection or severe disease?

6. Further immunological evidence is needed in the following areas to inform efficacy predictions:
    a. How do immune responses change over time; what is the durability of immune responses against SARS-COV-2 over the long-term? What is the impact of vaccine dose or interval on durability?

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   b. Which immune responses are most important for protection from infection (adaptive or innate immunity), severe disease or transmissibility? What is the role of humoral vs. cellular immunity in preventing immune escape of viral variants? What is the minimum magnitude of antibody response needed for protection?
   c. Are immunoglobulin (Ig)A/IgG/IgM antibodies protective against SARS-CoV-2 and what is the correlate of protection?

7. What level of COVID-19 vaccination coverage is required to achieve various public health milestones, including: coverage to reduce the burden on the health care system to a manageable degree, achieve herd immunity to protect non-vaccinated individuals, and remove public health measures (PHM) controls. What vaccine characteristics play the largest role on these milestones (i.e., efficacy, durability, uptake)?
8. What is the background level of Canadian vaccine-vector-specific responses (i.e., anti-Chimpanzee adenovirus)? Are these responses higher in some groups? Will these responses interfere with vaccine efficacy of these highly seropositive groups? What is the duration of anti-vector interference immunity following viral vector vaccines?
9. How will viral variants impact the efficacy, effectiveness, immunogenicity and safety of a vaccine with respect to death, severe disease, symptomatic disease, asymptomatic disease, infectivity and transmission? What is the effect of using booster vaccines containing heterologous antigens and what is the optimal timing for booster vaccination?
10. Are any components of the COVID-19 vaccine at high risk of inducing an anaphylactic reaction?
11. What is the incidence of rare, serious adverse events following immunization with COVID-19 vaccines?

    a. What is the incidence of thrombosis and thrombocytopenia including CVST and DIC after COVID-19 immunization and after infection with SARS-CoV-2? What is the trigger for the development of this adverse event following immunization and what can be done to mitigate its development?

    b. What is the exact biological mechanism by which viral vector vaccines may trigger VITT? Are VITTs a class effect of the adenovirus vector vaccines or are there separate mechanisms that are product-specific (e.g., due to differing dose and magnitude of immune response based on the nature of the vaccines)?

    c. How do age, sex, or other patient characteristics (e.g., pregnancy, health-seeking behaviours) affect the incidence of VITT and the complications of VITT?

12. Is there an association between myocarditis/pericarditis and mRNA COVID-19 vaccines? If so, what is the biological mechanism by which mRNA vaccines may trigger myocarditis/pericarditis? How do age, sex, other patient characteristics, or vaccine schedule affect the incidence of myocarditis/pericarditis following immunization with COVID-19 vaccines?
13. Does endemic coronavirus infection history impact the course of SARS-CoV-2 disease? Is there cross-protection or interference from antibodies/exposure to human seasonal coronaviruses when exposed to SARS-CoV-2 or vaccinated against SARS-CoV-2?

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14. Are there any negative interactions between COVID-19 vaccination and other medications? What is the recommended timing between COVID-19 vaccines and anti-SARS-CoV-2 prophylactic or therapeutic antibodies or convalescent plasma?
15. Does vaccination have an impact on the transmissibility of SARS-CoV-2 in individuals with asymptomatic infection?
16. What is the role of seasonal attenuation of SARS-CoV-2?
17. How does vaccination impact individual-level variation in transmission (e.g., superspreaders)?
18. What is the epidemiology of SARS-CoV-2 VOC over time and across the country and its regions? What are the transmissibility and virulence (including hospitalizations and deaths) of the VOC?
19. What are the epidemiological characteristics of breakthrough illness (e.g., vaccine recipient characteristics, SARS-CoV-2 VOC)?

Vaccine Administration

20. What is the efficacy, effectiveness, immunogenicity and safety of a mixed dose schedule or a mixed dose booster series?
21. What are the minimum, maximum and optimal intervals between doses of a two-dose COVID-19 vaccine schedule that continue to provide protection against disease?
22. Are any other vaccines (e.g., Bacillus Calmette-Guérin) protective against COVID-19 through off-target effects?
23. Can COVID-19 vaccine be simultaneously administered with other, non-COVID-19 vaccines (either live or inactivated vaccines)? What is the minimum interval between administration of a COVID-19 vaccine and other, non-COVID-19 vaccines (either live or inactivated vaccines)? What are the immunological and clinical outcomes if COVID-19 vaccines were simultaneously administered with other, non-COVID-19 vaccines?
24. What is the minimum interval required for vaccine administration following receipt of convalescent plasma or anti-SARS-CoV-2 spike protein monoclonal antibodies?

Standing Research Priorities

COVID-19 infection and disease

1. What is the epidemiological profile of COVID-19 (e.g., communicable period, all risk groups)?

    a. What is the disease distribution and spectrum of clinical illness for COVID-19, including burden of illness and risk by age, sex and other demographic variables associated with higher risk?
    b. What are the transmission dynamics of COVID-19, including degree of asymptomatic transmission, role of children in transmission, vertical transmissibility, onset and duration of viral shedding and communicable period, impact of changing weather conditions, and trends over time?

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   c. What are the rates of COVID-19 co-infections with other respiratory pathogens and what is the impact on pathogenesis and clinical outcomes?

2. Can COVID-19 vaccine be used to protect household contacts of a case from infection? Does COVID-19 vaccination decrease infectiousness and clinical illness in individuals that have already acquired infection? Is COVID-19 vaccination effective in interrupting transmission?

Ethics, Equity, Feasibility and Acceptability

3. What is the acceptability of (a) publicly funded COVID-19 vaccines and (b) other vaccines over time and over different epidemiological contexts among key populations, marginalized populations, providers and policy-makers in different epidemiological contexts across the country?
   a. What factors affect acceptability of immunization with a COVID-19 vaccine in these groups?
   b. What factors affect acceptability of immunization in general?
   c. How will acceptability of prioritized key populations for early immunization with COVID-19 vaccines evolve in different epidemiological contexts across the country?
   d. What strategies can improve acceptability of a COVID-19 vaccine in these groups?

4. How can vaccine allocation decisions be communicated to individuals and communities in order to maintain trust in public health authorities?

5. What COVID-19 vaccination strategies or implementation strategies can reduce health inequities in populations for whom the vaccination program is directly intended, and in populations for whom the vaccination program is not intended, but who are still impacted by it (e.g., impacted by the disease, spillover effects such as for caregivers, or externalities such as with herd immunity)?

6. Can a different COVID-19 vaccine be used to complete a primary series or as a booster dose? How are returning travellers managed if they have initiated but not completed a COVID-19 vaccine series abroad?

Health-Related Quality of Life and Well-being

7. What is the health-related quality of life or well-being of COVID-19 patients and caregivers over time (e.g., health utilities, patient-reported outcomes, patient-reported experiences measures)?

8. What is the impact of COVID-19 vaccination on health-related quality of life or well-being on individuals?

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VII. SURVEILLANCE ISSUES

Ongoing and systematic data collection, analysis, interpretation and timely dissemination is fundamental to planning, implementation, evaluation, and evidence-informed decision-making. To support such efforts, NACI encourages surveillance improvements in the following areas:

1. **Epidemiology**
    - Enhance social and socioeconomic data collected and made available to understand and address health inequities related to COVID-19
    - Systematic examination of the Canadian burden and epidemiology of COVID-19 outbreaks by setting and severity, identifying high-risk activities, settings and populations
    - Evaluation of the success of public health interventions to minimize or prevent COVID-19 outbreak events, especially in vulnerable or high-risk communities

2. **Laboratory (e.g., strain characterization)**
    - Enhance laboratory surveillance in order to provide early warning of increasing or decreasing activity by age, sex, and presence of symptoms, and help interpret case data based on changes to testing algorithms
    - Conduct genomic surveillance to identify international and inter-provincial transmission and new strains/variants with differing severity, transmissibility, or vaccine comparability
    - Explore other SARS-CoV-2 detection kits at point of care with immediate results
3. **Vaccine (coverage, effectiveness, safety)**
    - Reliably monitor coverage rates for each authorized COVID-19 vaccine in different key populations, ensuring data on series completion
    - Ensure existing mechanisms for the evaluation of adverse events are positioned to generate data for each authorized COVID-19 vaccine

TABLES

Table 6. Strength of NACI Recommendations

Strength of NACI Recommendation *based on factors not isolated to strength of evidence* (e.g., public health need)	**STRONG**	**DISCRETIONARY**
Wording	"*should/should not be* offered"	"*may/may not be* offered"
Rationale	Known/anticipated advantages outweigh known/anticipated disadvantages ("should"), OR Known/anticipated disadvantages outweigh known/anticipated advantages ("should not")	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists

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Implication	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may/may not be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

LIST OF ABBREVIATIONS

Abbreviation	***Term***
Ad26	Modified human adenovirus 26
AE	Adverse event
AEFI	Adverse event following immunization
ARCHE	Alberta Research Center for Health Evidence
CDC	Centres for Disease Control and Prevention (United States)
ChAd	Chimpanzee Adenovirus
CI	Confidence interval
CIC	Canadian Immunization Committee
CIG	Canadian Immunization Guide
CLS	Capillary leak syndrome
COVID-19	Coronavirus disease 2019
CVST	Cerebral venous sinus thrombosis
DART	Developmental and Reproductive Toxicity
DIC	Disseminated intravascular coagulation
EEFA	Ethics, Equity, Feasibility, and Acceptability
EMA	European Medicines Agency
FDA	Food and Drug Administration (US)
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	Human immunodeficiency virus
ICU	Intensive care unit
IM	Intramuscular
Ig	Immunoglobulin
IGRA	Interferon gamma release assay
JCVI	Joint Committee on Vaccination and Immunisation (UK)
MAAE	Medically attended adverse event
MenACWY	Quadrivalent meningococcal vaccine

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mRNA	messenger ribonucleic acid
OECD	Organisation for Economic Co-operation and Development
PF4	Platelet Factor 4
NACI	National Advisory Committee on Immunization
NITAG	National Immunization Technical Advisory Group
PCR	Polymerase chain reaction
PHAC	Public Health Agency of Canada
SAE	Serious adverse events
SAGE	Strategic Advisory Group of Experts on Immunization (WHO)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SD	Standard dose
SII	Serum Institute of India
SOC	System organ class
TST	Tuberculin skin test
TTS	Thrombosis with Thrombocytopenia Syndrome
UK	United Kingdom
US	United States
VIPIT	Vaccine-Induced Prothrombotic Immune Thrombocytopenia
VITT	Vaccine-Induced Thrombotic Thrombocytopenia
VOC	Variant of concern
VOI	Variant of interest
VPD	Vaccine preventable disease
WHO	World Health Organization

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ACKNOWLEDGMENTS

This statement was prepared by: SJ Ismail, K Young, MC Tunis, A Killikelly, R Stirling, O Baclic, J Zafack, M Salvadori, N Forbes, L Coward, C Jensen, R Krishnan, NK Abraham, Y-E Chung, B Warshawsky, E Wong, K Farrah, A Nam, C Quach, R Harrison, and S Deeks on behalf of the High Consequence Infectious Disease Working Group (HCID WG) and was approved by NACI.

NACI gratefully acknowledges the contribution of: C Quach, C Mauviel, K Ramotar, N St-Pierre, V Ferrante, S Pierre, E Tice, A Sinilaite, MW Yeung, Z Taha, N Alluqmani, SH Lim, L Whitmore, J Shurgold, J Vachon, J Macri, J Mielczarek, R Goddard, B Sader, M Patel, A House, and the Alberta Research Centre for Health Evidence, and the PHAC Public Health Ethics Consultative Group.

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APPENDIX A: CLINICAL TRIAL EVIDENCE SUMMARY FOR PFIZER-BIONTECH COVID-19 VACCINE

Study C4591001 is the pivotal Phase 1/2/3 trial for the Pfizer-BioNTech COVID-19 vaccine. Evidence on immunogenicity is available for participants aged 12 to 15, 16 to 55, and 65 to 85. Evidence on the safety and efficacy of the vaccine is available for adolescents 12-15 years of age and adults 16 years of age and older. Studies did not include participants from long term care facilities. The Phase 2/3 portion of the trial involved approximately 46,000 study participants randomized (1:1) to receive either the vaccine or placebo. The data presented below are for an interim analysis, therefore the time of follow-up is not consistent but was less than four months after the second dose (maximum of 14 weeks) for all participants.

Evidence from the ongoing Phase 2/3 trial (participants 16 years of age and older [138] and in adolescents 12 to 15 years of age [126]) were published in December 2020 and May 2021, respectively, after NACI's review of the evidence. Evidence from post-marketing surveillance and studies is found in the main body of this statement.

Efficacy

Severe outcomes due to COVID-19

There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death [139].

There may be a protective effect against severe COVID-19 outcomes for individuals 16 years of age and older when receiving at least one dose of vaccine (overall vaccine efficacy of 88.9%, 95% CI: 20.1 to 99.7%), based on one case identified in the vaccine group (N=21,669) and nine cases in the placebo group (N=21,686). Vaccine efficacy against severe COVID-19 disease was also examined after receipt of Dose 2 (from 7 days and 14 days after Dose 2), but there were an insufficient number of events reported (one severe outcome in the vaccine group and three in the placebo group for each outcome) to determine whether the vaccine was efficacious in reducing severe outcomes with any precision (i.e., the resulting point estimates had wide confidence intervals that included zero).

In adolescents 12 to 15 years of age, vaccine efficacy could not be assessed against severe outcomes as there were no confirmed cases of severe COVID-19 identified as of the date of data cut-off for the efficacy analysis. There were also no deaths identified in adolescent study participants during the clinical trial [126].

Symptomatic COVID-19 disease

In adults 16 years of age and older:

The estimated vaccine efficacy at least 7 days after Dose 2 was 94.6% (95% CI: 89.9 to 97.3%), with 9 confirmed symptomatic COVID-19 cases, as defined in trial protocol [138] identified among vaccine recipients (N=19,965) compared to 169 cases among placebo recipients (N=20,172). The vaccine efficacy at least 14 days after Dose 2 in this population was comparable (94.4%,

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95% CI: 89.1 to 97.3%). Results were similar when estimating the efficacy specifically in individuals without evidence of prior SARS-CoV-2 infection at 95.0% (95% CI: 90.3 to 97.6%) with 8 confirmed cases among vaccine recipients (N=18,198) compared to 162 cases among placebo recipients (N=18,325).

When adult study participants without evidence of prior SARS-CoV-2 infection were stratified by age, vaccine efficacy against COVID-19 from 7 days after Dose 2 was between 93.7% (>55 years) and 95.6% (16 to 55 years). In individuals ≥65 years of age, vaccine efficacy was 94.7% (95% CI: 66.7 to 99.9%), while in participants ≥75 years of age, the observed vaccine efficacy was 100% compared to placebo, but with a wide confidence interval including zero which resulted from an insufficient number of events reported (0 vs 5 cases, 95% CI: –13.1 to 100.0%). The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 91% (between 91.7% and 100.0%) in all subgroups stratified by "at risk" status (e.g., presence of a 1 or more comorbidities). The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 89% for all races (89.3 to 100%) and 94% for all ethnicities included in the sub-analysis (94.4 to 95.4%).

After Dose 1, but prior to administration of Dose 2, 39 COVID-19 cases were identified in the vaccine group (n=21,669) compared to 82 in the placebo group (n=21,686) for an overall estimated vaccine efficacy in participants 16 years of age and older of 52.4% (95% CI: 29.5 to 68.4%). If the analysis was restricted to cases identified only in the time period >14 days after Dose 1 to before Dose 2 the estimated vaccine efficacy increased to 92.3% (95% CI: 69 to 98%).

Table 7. Pfizer-BioNTech vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1 and before dose 2 in participants 16 years of age and older[a]

Time period of interest	Events in vaccine group (N=21,669)	Events in placebo group (N=21,686)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1 to before dose 2	39	82	52.4% (29.5 to 68.4%)
>14 days after dose 1 to before dose 2[b]	2	27	92.3% (69 to 98%)

[a] In the all-available efficacy population consisting of randomized study participants who received at least one dose of the study intervention (i.e., vaccine or placebo)

[b] Comité sur l'immunisation du Québec. Stratégie de vaccination contre la COVID-19 : report de la 2e dose en contexte de pénurie. Institut national de Santé Publique du Québec, 18 décembre 2020

In adolescents 12 to 15 years of age:
In study participants without prior evidence of SARS-CoV-2 infection, there were no confirmed COVID-19 cases occurring at least 7 days after Dose 2 among vaccine recipients (n=1,005) compared to 16 cases among placebo recipients (n=978) for an estimated vaccine efficacy against confirmed COVID-19 of 100.0% (95% CI: 75.3 to 100%) [126].

After Dose 1, but prior to administration of Dose 2, 3 COVID-19 cases were identified in the vaccine group (n=1,131) compared to 12 in the placebo group (n=1,129) for an overall estimated vaccine efficacy in adolescents 12 to 15 years of age of 75.0% (95% CI: 7.4 to 95.5%). If the analysis was restricted to case identified only in the time period ≥11 days after Dose 1 to before Dose 2, the estimated vaccine efficacy increased to 100% (95% CI: 41.4 to 100%).

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Table 8. Pfizer-BioNTech vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1 and before dose 2 in adolescents 12 to 15 years of age[a]

Time period of interest	Events in vaccine group (N=1,131)	Events in placebo group (N=1,129)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1 to before dose 2	3	12	75% (7.4 to 95.5%)
≥11 days after dose 1 to before dose 2	0	8	100% (41.4 to 100%)

[a] In the all-available efficacy population consisting of randomized study participants who received at least one dose of the study intervention (i.e., vaccine or placebo)

There is no analysis provided for efficacy specifically in individuals (any age range) with prior evidence of SARS-CoV-2 infection.

Asymptomatic infection and transmission
There are no efficacy data for these outcomes at this time.

Immunogenicity

Humoral immune responses
Both SARS-CoV-2 binding and neutralizing antibodies induced by this vaccine had similar trends across both adult age groups (18 to 55 and 65 to 85 years of age N=195). In adults, maximal immune responses were seen on day 28, 7 days after the second dose. Binding and neutralizing antibodies were both induced by one dose of vaccine and boosted by the second dose of vaccine. The immune response elicited by one dose accounted for 10-20% of the maximal immune response. Up to day 35, older adults (65-85 years of age) had a lower immune response compared to younger adults (18-55 years of age). After the peak on day 28, immune responses decreased until the final evaluation point on day 52, 30 days after dose 2 in younger adults, while no decrease was observed in older adults. SARS-CoV-2 neutralizing antibody responses one month following dose 2 were consistent, if not slightly higher, in adolescents 12-15 years of age compared to young adults 16-25 years of age. At every time point tested and across all included age groups, immune responses were higher than placebo.

Cellular immune responses
Cellular immune responses were assessed in the adult age groups (18 to 55 and 65 to 85 years of age). Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine, as demonstrated by the increase in these cell population percentages from day 1 to day 28. Increases were seen in both younger adults (18-55 years of age) and older adults (65-85 years of age). The characterization of these cells indicates a Th-1 biased cellular immune response. Intermediate time points were not reported.

Vaccine Safety and Adverse Events Following Immunization

Safety evidence for participants 16 years and older is based on interim analyses of 37,586 participants with a median of two months of follow-up (range: <2 weeks to <14 weeks) after Dose 2. About 19,000 participants had at least 2 months of follow-up, including about 9,500 who received the vaccine. Participants who inadvertently received the vaccine (n=12) or placebo (n=11) while pregnant are being followed. Safety evidence for adolescent participants 12 to 15

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years of age is based on interim analyses of 2,260 participants. Approximately 1,300 participants had at least 2 months of follow-up after Dose 2, of which 660 in this group received the vaccine.

Local Reactions

In vaccine recipients 12 years of age and older, the frequency of local reactions was similar after Dose 1 and Dose 2. Pain at the injection site was very common (occurring in up to 86% of adolescents 12 to 15 years of age after dose 1). Most local reactions among vaccine recipients were mild or moderate in severity, with any severe reactions being reported by ≤1% of participants. No Grade 4 local reactions were reported. Across all adolescent and adult age groups, local reactions after either dose had a median onset between zero and 2 days post-vaccination and a median duration of 1 to 3 days.

Systemic Reactions

Systemic events were generally increased in frequency and severity in vaccine recipients compared to placebo recipients, and in younger adults (16-55 years old) compared to older adults (≥56 years old), with frequencies and severity increasing with the number of doses (Dose 2 compared to Dose 1). Fatigue (34.1 to 59.4%), headache (25.2 to 51.7%), and muscle pain (13.9 to 37.3%) were very common in both younger and older adults and after Dose 1 and Dose 2, respectively. Fever was common after the first dose (3.7% of 16-55 year olds, 1.4% of >55 year olds) but was very common after the second dose (15.8% of 16-55 year olds, 10.9% of >55 year olds). Joint pain was very common or common in both younger and older adults (11.0 to 21.9% of 16-55 year olds, 8.6 to 18.9% of >55 year olds). Diarrhea was very common or common in both younger and older adults (10.0 to 11.0% of 16-55 year olds, 8.0% of >55 year olds), but was similar to rates seen in the placebo group and did not appear to differ between Dose 1 and Dose 2.

Systemic events were more frequent in adolescents compared to adults. In the adolescent group, fatigue (60.1 to 66.0%), headache (55.3% to 64.5%), chills (27.6 to 41.5%), muscle pain (24.1 to 32.4%) and fever (10.1 to 19.6%) were very common after Dose 1 and Dose 2, respectively. Joint pain was common after Dose 1 (9.7%) and very common after Dose 2 (15.8%). Vomiting (2.8 to 2.6%) and diarrhea (8.0 to 5.9%) were common after both Dose 1 and Dose 2, respectively.

For adolescents and adults, the median onset day for most systemic events after either dose of vaccine was 1 to 3 days post-vaccination, with a median duration of 1 day, except for fatigue and chills, which had median durations of 1 to 2 days. The majority of systemic events were mild or moderate in severity.

Overall, the frequency of any severe systemic event after Dose 1 was ≤0.9% in individuals 16 years of age and older. After Dose 2, severe systemic events had frequencies of <2% with the exception of fatigue (3.8%) and headache (2.0%). The proportion of participants that experience severe fever (>38.9°C to 40.0°C) increased between Dose 1 (0.2%) and Dose 2 (0.8%). Grade 4 fever (>40.0°C) was reported for 2 participants in each of the vaccine and placebo groups. In adolescents 12 to 15 years of age, the frequency of severe systemic events was ≤3.5%. Grade 4 fever (40.4 °C) was reported for 1 participant in the vaccine group.

Severe or Serious Adverse Events

Among adult participants 16 years of age and older in the vaccine group, 1.1% and 0.1% of participants experienced at least one severe AE and one life-threatening adverse events (AE), respectively, compared to 0.7% and 0.1% of participants in the placebo group. Among non-

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serious unsolicited adverse events, there was a numerical imbalance of four reports of Bell's palsy in the vaccine group compared with no report in the placebo group. These cases of Bell's palsy occurred 3, 9, 37, and 48 days following vaccination. Among adolescents 12 to 15 years of age in the vaccine group, 0.8% and 0.1% of participants experienced at least one severe AE and one life-threatening AE, compared to 0.3% and 0.1% of participants in the placebo group. In adolescents, no clinically meaningful differences were observed in AEs by age, sex, or race/ethnicity.

The proportions of adult participants 16 years of age and older who reported at least 1 serious adverse event (SAE) were similar in the vaccine group (0.5%) and in the placebo group (0.4%), and was lower in adolescents 12 to 15 years of age (0.4% in the vaccine group and 0.2% in the placebo group). In adults 16 years of age and older, three of the SAEs in the vaccine group and none in the placebo group were assessed by the investigator as related to the study intervention: 1 SAE each of shoulder injury related to vaccine administration, ventricular arrhythmia, and lymphadenopathy. No SAEs reported in adolescents 12 to 15 years of age were assessed by the investigator as related to the study intervention. No clinically meaningful differences in SAEs were observed by age, sex, or race/ethnicity. After either vaccine dose, no participant reported an immediate allergic reaction to vaccine.

Other serious adverse events

Lymphadenopathy

Lymphadenopathy was not a solicited AE. Among adult participants 16 years of age and older (n=37,586) who were followed for <2 weeks to <14 weeks after Dose 2, AEs of lymphadenopathy were reported in 0.3% (n=64) participants (0.5% [n=54] in the younger age group and 0.1% [n=10] in the older age group) in the vaccine group and 6 participants (0.0%) in the placebo group. Most lymphadenopathy events were reported within 2 to 4 days after vaccination. The average duration of these events was approximately 10 days, with 11 events ongoing at the time of the data cut-off. Vaccination-related lymphadenopathy in adolescents 12 to 15 years of age occurred in 0.6% of vaccine recipients (0.8% related and not related), and in 0.1% of placebo recipients (0.2% related and not related). Most cases were reported within 2 to 10 days after vaccination and approximately half resolved within 1 to 10 days, with others ongoing at the time of the data cut-off.

Appendicitis

Among adult participants 16 years of age and older who were followed <2 weeks to <14 weeks after Dose 2, there were a total of 12 participants with SAEs of appendicitis; 8 of which were in the vaccine group. Six of those 8 occurred in younger adults and 2 occurred in older adults. None of the cases were assessed as related to the vaccine by the investigators. The rate in either age group was not estimated to be greater than expected compared to baseline rates. Among adolescents 12 to 15 years of age, 1 participant in the vaccine group and 2 participants in the placebo group reported appendicitis. None were assessed as related to the vaccine by investigators.

Death

There were 6 adult participants (16 years of age and older) who died as of 14 November 2020, the data cut-off date for the interim analysis. This included 2 participants in the vaccine group and 4 participants in the placebo group. None of these deaths in the vaccinated group were assessed by the investigator as related to the vaccine. No deaths were reported in adolescents aged 12 to 15.

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APPENDIX B: CLINICAL TRIAL EVIDENCE SUMMARY FOR MODERNA COVID-19 VACCINE

Pivotal Phase 1, 2, and 3 trials are being conducted for the Moderna COVID-19 vaccine. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. Studies did not include participants from long term care facilities. The Phase 3 portion of the trial involved 30,413 study participants randomized (1:1) to receive either the vaccine (2 doses of 100 mcg) or placebo. The data presented beloware for an interim analysis, therefore the time of follow-up is not consistent but was a median of two months after the second dose (maximum of 14 weeks) for all participants. Evidence from post-marketing surveillance and studies is found in the main body of this statement.

Efficacy

Severe outcomes due to COVID-19
There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, as defined in the trial protocol [140].

The efficacy of the Moderna COVID-19 vaccine to protect against severe COVID-19 cases occurring at least 14 days after the second injection was in 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group). There were 30 confirmed severe COVID-19 cases in the placebo group compared to 0 cases in mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%).

Symptomatic COVID-19 disease
The primary efficacy outcome examined the efficacy of Moderna COVID-19 vaccine to protect against confirmed symptomatic COVID-19 starting 14 days after Dose 2 in study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline. This analysis included 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group), with a median time of follow-up after receiving the second injection of 63 days. There were 185 confirmed COVID-19 cases [141] occurring at least 14 days after the second injection among placebo recipients compared to 11 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.1% (95% confidence interval, CI: 89.3 to 96.8%).

A subgroup analysis of the interim primary efficacy outcome was conducted in three age groups: 18 to <65 years of age (10,521 participants in the placebo group and 10,551 participants in the Moderna COVID-19 vaccine group), ≥65 years of age (3,552 participants in the placebo group and 3,583 participants in the Moderna COVID-19 vaccine group), and a further subgroup of study participants ≥75 years of age (688 participants in the placebo group and 630 participants in the Moderna COVID-19 vaccine group).

In study participants 18 to <65 years, there were 156 confirmed COVID-19 cases occurring at least 14 days after the second injection among placebo recipients compared to 7 cases among mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 95.6% (95% CI: 90.6 to 97.9%). The corresponding incidence rate per 1,000 person-years (total time at risk in each treatment group) was 64.63 in the placebo group and 2.88 in the Moderna COVID-19 vaccine group. In study participants ≥65 years of age there were 29 confirmed COVID-19 cases among

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placebo recipients compared to 4 cases among Moderna COVID-19 vaccine recipients, corresponding to a somewhat lower point estimate of vaccine efficacy of 86.4% (95% CI: 61.4 to 95.2%). The corresponding incidence rate per 1,000 person-years was 33.73 in the placebo group and 4.60 in the Moderna COVID-19 vaccine group. In the subgroup of study participants ≥75 years of age there were 7 confirmed COVID-19 cases among placebo recipients compared to 0 cases among Moderna COVID-19 vaccine recipients, for a corresponding vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%), but this must be interpreted with caution as there were few events identified in this age group.

The efficacy of the Moderna COVID-19 vaccine to protect against confirmed COVID-19 cases occurring at least 14 days after the second injection was also assessed in participants most at risk for severe complications of COVID-19. In study participants 18 to <65 years of age and at risk for severe complications of COVID-19 (2,118 participants in the placebo group and 2,155 participants in the Moderna COVID-19 vaccine group) there were 35 confirmed COVID-19 cases in the placebo group compared to 2 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.4% (95% CI: 76.9 to 98.7%). In study participants 18 to <65 years of age, but not at risk for severe complications of COVID-19 (8,403 participants in the placebo group and 8,396 participants in the Moderna COVID-19 vaccine group) the estimated vaccine efficacy was 95.9% (95% CI: 90.0 to 98.3%) based on 121 confirmed COVID-19 cases in the placebo group and 5 cases among Moderna COVID-19 vaccine recipients. Vaccine efficacy estimates were also calculated for select individual co-morbid conditions; however, as of November 7, 2020 the number of identified events in these subgroups (n=0 to 11) were too small for meaningful analysis.

A secondary analysis of vaccine efficacy to protect against the first occurrence of confirmed COVID-19 starting 14 days after Dose 2 regardless of prior SARS-CoV-2 infection, as determined by serologic titre, involved the full analysis set (randomly assigned study participants who received at least one injection). There were 30,351 study participants 18 years of age or older (15,170 participants in the placebo group and 15,181 participants in the Moderna COVID-19 vaccine group). There were 187 confirmed COVID-19 cases among placebo recipients compared to 12 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 93.6% (95% CI: 88.6 to 96.5%). However, there was a small proportion of study participants enrolled (n=679/29,148; 2.3%) with positive SARS-CoV-2 infection status at baseline.

In participants who had only received one dose of vaccine at the time of data analysis (placebo group: n=1,079; vaccine group: n=996), vaccine efficacy was 80.2% (95% CI: 55.2 to 92.5%). Limiting the analysis to 14 or more days after Dose 1, efficacy rose to 92.1% (95% CI: 68.8 to 99.1%). However, there are limited data on the efficacy of Dose 1 alone beyond 28 days post-vaccination.

Table 9. Moderna vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1[a]

Time period of interest	Events in vaccine group (N=996)	Events in placebo group (N=1,079)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1	7	39	80.2% (55.2 to 92.5%)
>14 days after dose 1	2	28	92.1% (68.8 to 99.1%)

[a] In the modified intention-to-treat population consisting of randomized study participants who had received only one dose of their assigned intervention (i.e., vaccine or placebo) at the time of analysis

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Asymptomatic infection and transmission
Nasopharyngeal swabs for SARS-CoV-2 virus were collected for all participants at specified intervals before Dose 1 and before Dose 2. There were 14 participants in the vaccine arm who were previously seronegative before administration of Dose 1 who had asymptomatic infection at the second time point, compared to 38 participants in the placebo arm. No formal efficacy data are available; however, assessment of this outcome is ongoing.

Immunogenicity

Humoral immune responses
Antibodies that bind the spike protein were induced in vaccine recipients by day 15 (15 days after dose 1) and reach maximum levels on day 43 (15 days after dose 2). Maximal binding antibody responses approximate the levels of the highest affinity samples of convalescent sera. Binding antibodies reached elevated levels on day 36 (7 days after dose 2) and persisted but decreased through day 119 (90 days after dose 2), the last day for which data is available.

Binding antibodies induced by 1 dose of the vaccine (i.e., on day 29) were 10-20% of the elevated responses seen on day 36. It is unknown how binding antibody responses change over time. Binding antibody responses through day 36 seems to be approximately equivalent across age groups. The data may suggest an age-dependent binding antibody durability. Antibody responses for age 70 or below decreased more slowly than for those above 70.

Neutralizing antibodies were not induced to the level of convalescent sera until day 36, 7 days after dose 2 for all age groups. Neutralizing antibody responses through day 36 seems to be approximately equivalent across age groups. Neutralizing antibody responses on Day 119 represent a larger proportion of the maximum on day 43, compared to binding antibody responses. This may indicate increased durability of neutralizing antibody responses compared to binding antibody responses. These neutralizing data may also suggest an age-dependent neutralizing antibody durability as antibody responses on day 119 for each cohort were inversely proportional to the age of the cohort.

Immunogenicity data from the Phase 1 trial of the Moderna COVID-19 vaccine in a small number of subjects (n=33) demonstrate antibody persistence for 6 months [142].

Cellular immune responses
Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine. Maximal induction of both CD4+ and CD8+ T cells was observed on day 43, 14 days after dose 2. The percentage of CD8+T cells was lower for all age groups compared to CD4+ T cells. By comparing the percentage of cells that express Th-1 (IFN gamma, IL-2, TNF) vs. Th-2 (IL-4 and IL-13), it was demonstrated that this vaccine induces a Th1-biased cellular immune response.

Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 30,351 participants with a median follow-up time of 63 days after Dose 2 (92 days after Dose 1). 23,276 participants had at least one month of follow-up after Dose 2 (12,021 individuals received the vaccine) and 7,667 individuals had at least 2 months of follow-up after Dose 2 (3894 individuals received the vaccine) [141]. Participants who inadvertently received the vaccine (n=6) or placebo (n=7) while pregnant are being followed.

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Solicited Local Reactions

In vaccine recipients, frequency of local reactions increased from Dose 1 to Dose 2. Pain at the injection site was very common (occurred in 83.7% of vaccine recipients after Dose 1 and in 88.2% of vaccine recipients after Dose 2). Redness was common (2.8 to 8.6%) and swelling was common to very common (6.1 to 12.2%). Grade 3 (severe) reactions were reported by 3.5% and 7.0% of vaccine recipients after Dose 1 and Dose 2, respectively [141]. No Grade 4 local reactions were reported. The majority of local reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 3 days. Delayed injection-site reactions (i.e., with onset on day 8 or after) were noted in 0.8% of participants after the first dose and in 0.2% of participants after the second dose. Reactions were characterized by erythema, induration, and tenderness, and they resolved within 4 to 5 days.

Localized axillary swelling and tenderness was solicited and occurred in less than 5% of placebo recipients after any dose, and 10.2% and 14.2% of vaccine recipients after Dose 1 and 2, respectively. Among vaccine recipients, the incidence of severe (Grade 3) axillary swelling and tenderness increased from Dose 1 to Dose 2 (0.3 to 0.5%), whereas in the placebo group it decreased from Dose 1 to Dose 2 (0.2 to 0.1%) [141].

Solicited Systemic Reactions

Systemic events generally had a higher frequency and severity in vaccine recipients compared to placebo recipients, with frequency and severity increasing with the number of doses (Dose 1 compared to Dose 2). In vaccine recipients, fatigue (37.2 to 65.3%), headache (32.6 to 58.6%), muscle pain (22.7 to 58.0%), and arthralgia (16.6 to 42.8%) were very common in all age groups and after Dose 1 and Dose 2, respectively. Chills and nausea/vomiting were very common or common (8.3 to 44.2% and 8.3 to 19.0%, respectively). Fever was uncommon after the first dose (0.8%) but was very common after the second dose (15.5%).

Grade 3 reactions were reported by 2.9% and 15.7% of vaccine recipients after Dose 1 and Dose 2, respectively [141]. After Dose 2, Grade 3 fever (1.3%), headache (4.3%), fatigue (9.4%), myalgia (8.7%), arthralgia (5.1%), and chills (1.3%) were common. The proportion of vaccine recipients that experience Grade 3 fever (>38.9°C to 40.0°C) increased between Dose 1 (<0.1%; n=11) and Dose 2 (1.3%; n=202). Among placebo recipients only 2.7% reported Grade 3 adverse events after either dose.

The incidence of any Grade 4 events was <0.1% after both doses in both vaccine (6 to 12 events) and placebo (2 to 4 events) recipients. Grade 4 fever (>40.0°C) was reported for 4 placebo recipients and 4 vaccine recipients after Dose 1, and 2 placebo recipients and 12 vaccine recipients after Dose 2. The majority of systemic reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 2 days.

Unsolicited Severe or Serious Adverse Events

During the first 28 days after any dose, 1.5% and 0.5% of participants in the vaccine group (Dose 1 and Dose 2, respectively) reported unsolicited severe and serious AEs (SAEs), compared to 1.3% and 0.6% of participants in the placebo group. There was no apparent effect of age on the relative incidence of SAEs in the vaccinated or placebo group. There were three reports of Bell's palsy in the vaccine group which occurred 22, 29, and 32 days after the second dose and one in the placebo group which occurred 17 days post injection. One case of Bell's

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palsy in the vaccine group was considered a SAE (67-year-old female with diabetes who was hospitalized for stroke due to new facial paralysis 32 days after vaccination).

Three SAEs in vaccinated individuals were considered by the study sponsor to be related to the trial intervention: two cases of facial swelling and one case of nausea and vomiting with headaches and fever.

Four additional SAEs in vaccine recipients and five SAEs in placebo recipients were considered to be related to the trial intervention by trial investigators [141]. Of the SAEs considered related to the Moderna vaccine, 2 cases of autoimmune diseases were reported: one rheumatoid arthritis in a participant known with hypothyroidism, that was unresolved at the time of the report and one autonomic dysfunction in a participant known with hypothyroidism, also unresolved at the time of the report. In the placebo group, one participant (known to have chronic back pain) developed polymyalgia rheumatica, which was resolving.

No clinically meaningful differences in SAEs were observed by age. Sex and race/ethnicity were not assessed. After either vaccine dose, no participant in the Phase 3 study reported an immediate allergic reaction to vaccine.

Other serious adverse events

Facial swelling

Two female participants with a history of dermal filler injection in the cheeks experienced facial swelling 1 to 2 days following immunization. Both were treated and the swelling resolved after a duration of about 5 days. A third female participant with a history of dermal filler injection in the lips had lip angioedema 2 days after vaccination which was classified as medically significant but not considered as an SAE. The management and duration of this third event were not specified.

Death

A total of 13 deaths were reported, 6 in the vaccine group and 7 in the placebo group. None of these deaths were assessed to be related to any study intervention or COVID-19.

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APPENDIX C: CLINICAL TRIAL EVIDENCE SUMMARY FOR ASTRAZENECA COVID-19 VACCINE

Results from four clinical trials (two Phase 1/2, one Phase 2/3, and one Phase 3) were available at time of authorization for the AstraZeneca COVID-19 vaccine. Results from an ongoing Phase 3 trial in the United States (US) were not available at time of writing. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. The Phase 2/3 trial (COV002) trial and Phase 3 trial (COV003) assessed efficacy, safety and immunogenicity of the vaccine. The Phase 2/3 trial was based in the United Kingdom, (UK) while the Phase 3 trial was based in Brazil. These two studies underwent a series of protocol amendments and logistical challenges during the conduct of the trials that resulted in significant changes to the trials' methodology. There were changes from a single to a two-dose vaccine regimen, the use of both a low dose/standard dose (LD/SD) (in COV002 only, due to dosing error) and standard dose/standard dose (SD/SD) vaccine regimen, and the recruitment of progressively older study participants (56–69 and then ≥70 years of age) after the initial focus on adults 18–55 years of age. In the SD/SD vaccine regimen, study participants were randomized (1:1) to receive either the AstraZeneca COVID-19 vaccine, AZD1222 (5×10^{10} viral particles per 0.5 mL dose) or control injection. The participants randomized to the control group were administered two doses of quadrivalent meningococcal vaccine (MenACWY) (COV002) or MenACWY for Dose 1 and placebo for Dose 2 (COV003).

There were significant differences in the baseline characteristics of participants in the Phase 2/3 and Phase 3 trials. In addition, the clinical trials prioritized the recruitment of health care professionals and other adults with high potential for exposure to SARS-CoV-2, including health care and social setting workers.

Evidence from the AstraZeneca COVID-19 vaccine trials has been published [143]. Evidence from post-marketing surveillance and studies is found in the main body of this statement.

Efficacy

The estimates of vaccine efficacy for the AstraZeneca COVID-19 vaccine (AZD1222) come from the Phase 2/3 and Phase 3 trials. As of a data cut-off date of November 4, 2020 the primary analysis population (study participants who received either the LD/SD or SD/SD regimens) for the primary outcome included 11,636 participants seronegative at baseline (5,807 in the vaccine group, 5,829 in the control group). Of this population, 8,895 study participants (4,440 vaccine recipients and 4,455 controls) received the SD/SD regimen. As of a data cut-off date of December 7, 2020, the SD/SD population had increased to include 12,158 study participants (6,085 vaccine recipients and 6,073 controls). Unless otherwise noted, all data presented in this summary is based on the SD/SD vaccine regimen and as of a data cut-off date of December 7, 2020.

Symptomatic COVID-19 disease

The primary efficacy outcome assessed in the two trials was prevention of the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2, based on assessments of cases by an Adjudication Committee blinded to participant group assignment, and analysed in the combined LD/SD and SD/SD regimen population. Assessment in the subgroup that only received SD/SD was a pre-specified secondary analysis in the clinical trial. Symptomatic

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COVID-19 was defined as having at least one of the following symptoms (objective fever ≥37.8 C, cough, shortness of breath, and anosmia or ageusia) AND a swab positive for SARS-CoV-2 by RT-PCR AND confirmed by an Adjudication Committee.

Based on data as of December 7, 2020, there were 12,158 study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline (6,085 vaccine recipients and 6,073 controls) included as part of the SD/SD regimen analysis. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants receiving the SD/SD vaccine regimen was 62.5% (95% CI: 50.7 to 71.4%), based on identification of 71/6,085 (1.2%) cases in vaccine recipients and 186/6,073 (3.1%) in controls. The estimated vaccine efficacy by age was 63.1% (51.1 to 72.1%) in study participants 18-64 years of age and 50.7% (-65.8 to 85.4%) in participants ≥65 years of age. An ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18–55 years of age who received the SD/SD dosing regimen. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 59.3% (95% CI: 25.1 to 77.9%) in this age group. This analysis included study participants with any interval duration between doses.

Symptomatic COVID-19 by interval

As of December 7, 2020, the majority of study participants in the COV002 (UK) and COV003 (Brazil) clinical trials received the two doses of the SD/SD regimen within a 4–8 week (UK: 45.6%, Brazil: 87.2%) or a 9–12-week interval (UK: 34.4%; Brazil: 10.5%). About 1 in 5 study participants in the UK clinical trial (18.9%) received the SD/SD regimen with a >12-week interval between vaccine doses, and in the Brazil trial it was less than 1 in 50 study participants (1.8%). A very small proportion of study participants received the SD/SD regimen with a <4-week interval between doses (UK: 1.0%, Brazil: 0.4%).

An exploratory analysis examined the potential effect of the interval between the administration of the first and second vaccine doses on vaccine efficacy in study participants receiving the SD/SD vaccine regimen. Table 10 summarizes the estimates of vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 by dosing interval. There is a suggestion of an increase in the point estimate of vaccine efficacy with increasing intervals between the first and second dose of vaccine. However, it is important to note that the confidence intervals around these point estimates overlap.

Table 10. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2 in all participants, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks	67/5,473 (1.2)	162/5,422 (3.0)	59.6% (46.4 to 69.6%)
4 – 8 weeks	52/4,188 (1.2)	113/4,098 (2.8)	55.7% (38.5 to 68.1%)
9–12 weeks	15/1,285 (1.2)	49/1,324 (3.7)	69.0% (44.8 to 82.6%)
>12 weeks	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

In a subgroup analysis in study participants who received the SD/SD vaccine regimen, vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 was estimated by dosing interval and age group. These ad-hoc subgroup analyses were performed in participants 18-55 years of age from the COV002 (UK) clinical trial and in all study participants

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who received the SD/SD regimen (from COV002 and COV003), dichotomized into groups 18–64 years and ≥65 years of age.

The ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18-55 years of age who received the SD/SD regimen at an interval of >8 weeks between doses. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 65.6% (95% CI: 24.5 to 84.4%). In the updated dataset as of December 7, 2020, there were 1,375 study participants ≥65 years of age (699 in the vaccine group and 676 in the control group). Efficacy estimates for participants ≥65 years for the overall 4–12-week dosing interval and the 4–8-week interval have wide confidence intervals that include zero. Estimates of vaccine efficacy could not be calculated for participants ≥65 years for the 9–12-week and >12-week dosing intervals due to a lack of older study participants who received the SD/SD regimen during these dosing intervals (Table 11).

Table 11. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after dose 2, by dosing interval and age group (SD/SD seronegative baseline efficacy set[a])

Dosing interval and age group	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks			
18–64 years	63/4,790 (1.2)	156/4,760 (3.0)	60.5% (47.1 to 70.5%)
≥65 years	4/683 (0.6)	6/662 (0.9)	43.2% (-99.3 to 83.8%)
4 – 8 weeks			
18–64 years	48/3,506 (1.4)	107/3,439 (3.1)	56.6% (39.1 to 69.1%)
≥65 years	4/682 (0.6)	6/659 (0.9)	43.4% (-98.5 to 83.9%)
9–12 weeks			
18–64 years	15/1,284 (1.2)	49/1,321 (3.7)	69.0% (44.8 to 82.6%)
≥65 years	0/1 (0)	0/3 (0)	No estimate
>12 weeks			
18–64 years	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)
≥65 years	0/0 (0)	0/0 (0)	No estimate

[a]Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Symptomatic COVID-19 by presence of co-morbidity

Efficacy was also assessed based on the presence of comorbidity, which was defined as the presence of one or more of the following mild to moderate and controlled medical conditions at baseline: cardiovascular disease, respiratory disease, diabetes, or obesity (BMI ≥30 kg/m^2) based on a data cut-off date of November 4, 2020. For this exploratory analysis, included study participants who were SARS-CoV-2 seronegative at baseline and received the SD/SD regimen. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants without comorbidities was 58.0% (95% CI: 25.8 to 76.2%), based on 17/2,825 (0.6%) cases identified in the vaccine group compared to 39/2,774 (1.4%) cases in the control group. The corresponding estimate of vaccine efficacy in study participants with comorbidities was 67.1% (95% CI: 33.2 to 83.8%), based on the identification of 10/1,611 (0.6%) cases in the vaccine group compared to 32/1,670 (1.9%) cases in the control group.

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Symptomatic COVID-19 after one dose

Efficacy at various time points after one dose of AstraZeneca COVID-19 vaccine was assessed as a secondary/exploratory analysis based on data as of the interim analysis cut-off date of November 4, 2020 (Table 12). The analysis involved study participants who were SARS-CoV-2 seronegative at baseline and received SD vaccine as their initial vaccine dose. The median duration of follow-up after Dose 1 was 115 days (range: 41–149 days). Note that approximately 80% of study participants in the vaccine arm received the second dose of the vaccine; therefore, several estimates of vaccine efficacy are not solely due to the one dose of SD vaccine.

Table 12. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning after Dose 1, (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Events in vaccine group (AZD1222)	Events in control group (MenACWY)	Estimate of vaccine efficacy (95% CI)
After Dose 1	92 (N=8,008)	185 (N=8,013)	50.5% (36.5 to 61.5%)
≥22 days after Dose 1	51 (N=6,307)	141 (N=6,297)	64.1% (50.5 to 73.9%).
≥22 after Dose 1 but before Dose 2	15 (N=6,310)	52 (N=6,296)	71.3% (49.0 to 83.8%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Severe outcomes due to COVID-19

Severe COVID-19 disease

Severe COVID-19 disease, defined as study participants who met the confirmed COVID-19 case definition and were assigned a severity score of ≥6 on the World Health Organization Clinical Progression Scale (e.g., clinical severity requiring hospitalization, and may include intubation and mechanical ventilation, and death), was assessed as a secondary analysis of vaccine efficacy. Analysis included study participants who had been followed for ≥15 days since Dose 2, who were seronegative for SARS-CoV-2 at baseline, and received both doses of the SD/SD regimen. As of December 7, 2020, there were 6,085 study participants in the vaccine group and 6,073 participants in the control group. There was 1 case of severe COVID-19 disease identified in a study participant in the control group who received the control intervention within the 4–12-week dosing interval. This participant also required ICU admission and eventually died. An additional severe case occurred >21 days after the first dose and ≤14 days after the second dose in a study participant in the control group.

Hospitalizations

Vaccine efficacy against COVID-19 associated hospitalizations was assessed at multiple time points (Table 13). Assessment included study participants who were seronegative for SARS-CoV-2 at baseline and received both doses of the SD/SD regimen. After Dose 2 (median follow-up duration: 36 days, range: 1–79 days, based on data as of November 4, 2020), there were 7 hospitalizations due to COVID-19 identified in study participants who received the SD/SD regimen within the 4–12-week dosing interval, all in participants in the control group. There were no hospitalizations in the vaccine group ≥22 days after Dose 1; however, there were 2 cases hospitalized due to COVID-19 identified in the vaccine group and 16 in the control group ≥15 days after Dose 1, resulting in an estimate of vaccine efficacy of 87.6% (95% CI: 46.0 to 97.2%). The 2 hospitalizations in the vaccine group were 1 and 10 days post vaccination (median follow up: 115 days, range: 41–149).

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Table 13. Estimates of vaccine efficacy against hospitalization, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]	0/6,307 (0.0)	9/6,297 (0.1)	100% (95% CI: 49.6 to NE)
≥15 days after Dose 2[c]	0/6,085 (0.0)	7/6,073 (0.1)	N/A

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

Deaths

As of the updated data cut-off date of December 7, 2020, there has been a single death due to COVID-19 identified in a study participant in the control group.

Asymptomatic infection and transmission

This was an exploratory analysis conducted only in clinical trial COV002 (UK). As part of the study protocol, beginning one week after receipt of Dose 1, study participants were asked to provide weekly self-administered nose or throat swabs for RT-PCR testing. Participants were asked to report symptoms when they appeared; however, the presence or absence of symptoms at the time of sample collection was not routinely collected. An asymptomatic infection was defined as a study participant with a swab virologically confirmed for SARS-CoV-2 and who reported no clinical trial–defined symptoms of confirmed COVID-19. Study participants with virologically confirmed SARS-CoV-2 infection, but who did not report whether or not they had symptoms were classified as "unknown symptoms".

Table 14. Estimates of vaccine efficacy against asymptomatic infection, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]			
	14/3,060 (0.5%)	15/3,064 (0.5%)	6.6% (-93.5 to 54.9%)
≥15 days after Dose 2[c]			
Any interval	8/2,377 (0.3%)	11/2,340 (0.5%)	26.9% (-81.5 to 70.6%)
4–12 weeks	N/A	N/A	37.7% (-90.1 to 79.6%)
>12 weeks	N/A	N/A	-4.3% (-416.5 to 79.0%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

An additional ad-hoc analysis combining study participants with SARS-CoV-2 asymptomatic infection or associated with unknown symptoms also failed to demonstrate the efficacy of the SD/SD regimen (3.9%, 95% CI: -72.1 to 46.4%), based on the identification of 22 cases in the vaccine group and 23 cases in the control group ≥15 days after Dose 2.

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Immunogenicity

Approximately 15% of the overall safety analysis set was targeted for inclusion in the immunogenicity analysis set. These analyses combined evidence from SD/SD and LD/SD dosing regimens, and may not completely align with the data from individual studies.

Humoral immune responses
Antibody responses, both binding and neutralizing, differed for seronegative and seropositive vaccine recipients. Vaccine recipients who were seropositive at baseline demonstrated high antibody titres 28 days after Dose 1 compared to seronegative recipients. Seronegative recipients demonstrated an increase in their immune responses 28 days after Dose 2. By contrast, seropositive recipients had decreased immune responses after Dose 2 compared to responses after Dose 1. However, immune responses for seropositive recipients at all time points were higher than those for seronegative recipients. The mechanism behind these differences, and their potential impact on vaccine efficacy and effectiveness remains unclear. A recently published article contains additional evidence on humoral responses [128].

Antibody responses, both binding and neutralizing, were lower in older adults (65+) than in younger adults after both the first and second dose of vaccine. Without a correlate of protection, the significance of these difference in antibody responses is unclear.

Cellular immune responses
Cellular immune responses were elicited by this vaccine. The first dose elicited Th-1 biased CD4+ T cells in both younger and older age groups. Younger vaccine recipients exhibited higher cellular immune responses than older age groups. Notably, the second vaccine dose did not augment cellular immune responses. The mechanism and the impact on vaccine efficacy and effectiveness remains unclear.

Anti-Vector immune responses
It is unclear to what extent pre-existing immunity to any adenovirus-based vaccine vector exists in the Canadian population and what impact that could have on adenovirus-based vaccine safety and efficacy. It is also unclear as to what extent immunization with adenovirus-based vaccines elicits anti-vector immune responses and what impact that could have on homologous or heterologous booster doses with adenovirus-based vaccines. Evidence for a viral vector vaccine based on human adenovirus 5 (not authorized in Canada) indicated that vaccine recipients with high pre-existing immunity to the adenovirus vector had lower anti-SARS-CoV-2 immune responses [144]. The AstraZeneca COVID-19 vaccine uses a modified chimpanzee adenovirus vector (ChAd). AstraZeneca found no correlation between anti-ChAd neutralizing antibody responses and anti-SARS-CoV-2 immune responses. It also found that neutralizing antibody levels were not boosted after receiving the second dose. However, neutralization is not the only anti-vector immune response that could impact vaccine-induced immunity. It remains unclear if immune responses to the ChAd vector will impact the efficacy or effectiveness of this vaccine.

Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 23,745 participants of which 12,021 received at least one dose of the AZ COVID-19 vaccine and 11,724 received a control. The safety analyses were conducted in different analysis sets. Solicited adverse events occurring within 7 days after any dose were assessed among 2648 vaccine recipients who received at least one

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dose (SD) and 2497 control recipients. Approximately one third of study participants received their second vaccine dose within 6 weeks of receiving Dose 1. The majority (~90%) of study participants in the safety cohort were less than 65 years of age. The median duration of follow-up was 105 days post-Dose 1 and 62 days post-Dose 2.

Solicited Local Reactions

Solicited local injection site AEs were reported by 74.7% of evaluated participants within the first 7 days following any vaccine dose. Pain and tenderness were most frequently reported (54.2% and 63.7%, respectively) followed by warmth (17.7%), bruising (17.3%), redness (14.0%), pruritus (12.7%), and swelling (10.0%). The majority of solicited local reactions among vaccine recipients were mild or moderate in severity, with any grade 3 or 4 reactions being reported by ≤9.5% of participants. No Grade 4 AEs were reported. Local reactions were generally milder and reported less frequently after the second dose of the vaccine. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose within 6 weeks following Dose 1 (38.0% versus 58.3% to 74.3% when Dose 2 was provided after ≥6 weeks).

Solicited Systemic Reactions

Solicited systemic AEs were reported by 73.0% of evaluated participants within the first 7 days following any vaccine dose. The most common systemic solicited systemic AEs were fatigue (53.1%) and headache (52.6%). Other frequently reported systemic solicited AEs were muscle pain (44.0%), malaise (44.2%), feverishness (33.6%), chills (31.9%), joint pain (26.4%), nausea (21.9%) and fever ≥38.0°C (7.9%). Overall, the frequency of any grade 3 or 4 reaction was ≤8.3%. The single reported Grade 4 event was fever > 40°C. Across study groups, AEs were milder and reported less frequently after the second vaccine dose. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose at <6 weeks following Dose 1 (37.6% versus. 49.2% to 67.1% when Dose 2 was provided after at ≥6 weeks).

Unsolicited Serious Adverse Events

SAE were reported by less than 1% of study participants and was similar between the vaccine and control groups (0.7% and 0.8%, respectively). There were no clear imbalances by System Organ Class (SOC). The most frequently reported SAEs by SOC were 'Infections and Infestations' (0.1% vs 0.2%) and 'Injury, poisoning and procedural complications' (<0.1 % vs 0.1%).

Two SAEs (pyrexia, transverse myelitis) in the vaccine recipients were considered related to the vaccine by the study investigators. The case of pyrexia (40.5° C) occurred 2 days after dose 1 and resolved the same day following the administration of acetaminophen. The event of transverse myelitis occurred in a 37-year-old female with a family history of Charcot-Marie-Tooth type 1a (mother and brother). The participant received two doses of study intervention 77 days apart. Two weeks after the second dose, the participant developed sensory changes and clumsiness. Magnetic resonance imaging showed a lesion consistent with transverse myelitis or anterior spinal infarction. A third SAE was originally identified (C-reactive protein increase); However, after the cut-off date, causality for the SAE of C-reactive protein increase was updated by the investigator to be not treatment related.

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Other serious adverse events

Demyelinating events

An event of multiple sclerosis occurred in a 37-year-old female who developed sensory symptoms about 10 days after first (and only) vaccination. The clinical episode had a duration of 3 weeks. Further follow up with MRI of spine and brain showed an acute spinal lesion and older cerebral lesions, revealing pre-existing, but previously unrecognized, multiple sclerosis.

Death

A total of 6 deaths were reported among study participants (2 in the vaccine group and 4 in the control group). The cause of death among vaccine recipients included malignant neoplasm and fungal pneumonia, with neither considered to be related to the study intervention by the investigators.

Vaccine-Induced Immune Thrombotic Thrombocytopenia

Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been reported in Canada and globally following post-licensure use of AstraZeneca COVID-19 vaccine. Cases have usually occurred between 4 and 28 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the viral vector COVID-19 vaccines may trigger VITT is still under investigation. At this time, no other predisposing factors have consistently been identified in patients who develop VITT. The rate of this adverse event is still to be confirmed but had been most commonly estimated to be between 1 in 26,000 and 1 in 100,000 persons vaccinated with a first dose of AstraZeneca COVID-19 vaccine although this continues to evolve and may increase. Based on available evidence as of June 1st, 2021, PHAC has estimated the rate of VITT in Canada to be 1 in 73,000 doses administered. However, as investigations continue, this rate could be as high as 1 in 50,000 persons vaccinated with the COVISHIELD COVID-19 vaccine. The frequency of TTS following a second dose of AstraZeneca vaccine is currently reported as approximately 1 in 600,00 to 1 in 750,000 individuals vaccinated with a second dose, based on vaccine safety surveillance data from the United Kingdom but this continues to evolve [2]. Additional information is currently being gathered to characterize the rate of VITT more accurately. Based on available information, the case fatality of VITT typically ranges between 20 and 50%. Case fatality may vary with increased awareness of the adverse event and appropriate early treatment.

Effectiveness in individuals ≥65 years of age

In the absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on real-world vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized below.

All three observational studies assessed one dose of either the Pfizer-BioNTech or the AstraZeneca vaccines in the United Kingdom. The results below pertain only to the AstraZeneca portion of the studies. The studies were conducted during the period when the B.1.1.7 (Alpha) variant was rapidly becoming the dominant circulating strain in their respective geographic regions. Approximately 50% of laboratory samples were found to have a profile consistent with the B.1.1.7 (Alpha) variant in early December, 2020 in England, and 43% in

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Scotland in early January, 2021. By mid to late February, the B.1.1.7 (Alpha) variant represented almost 100% of circulating strains in England, and was considered the dominant strain in Scotland.

Overall summary of evidence:

In adults 65 years of age and over, observational data available from pre-prints from the United Kingdom have shown a reduction in the risk of symptomatic disease and hospitalization starting from two weeks following one dose of AstraZeneca vaccine.

Detailed summary of each study:

1. Hyams et al., Assessing the Effectiveness of BNT162b2 and ChAdOx1nCoV-19 COVID-19 Vaccination in Prevention of Hospitalisations in Elderly and Frail Adults: A Single Centre Test Negative Case-Control Study. SSRN-Lancet **preprint.** March 3, 2021. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3796835

Description: Test-negative case control study of hospitalized people ≥80 years of age (many of whom were frail with comorbidities) in two hospitals in Bristol, United Kingdom. Vaccination was determined by record linkage and adjustment was conducted for a number of factors. Vaccine effectiveness against hospitalization was assessed in those who had been vaccinated ≥14 days before symptom onset.

Results: One-dose vaccine effectiveness of 80.4% (95% CI: 36.4 – 94.5%) against hospitalization occurring within 14 or more days (maximum 53 days) after one dose of AstraZeneca COVID-19 vaccine among patients ≥80 years of age.

Review:

- Vaccination was determined by record linkage and clinical information was obtained from records by individuals who are blinded to the participants SARS-CoV-2 results. These are methodological strengths of this study.
- The authors performed a sensitivity analysis of those with symptom onset < 14 days after vaccination and did not find an effect, which is expected as this is too early for the vaccine to work, and adds strength to differences they note 14 days or more after vaccination.
- Eligible cases and controls were selected from the medical admission list, and it is unclear how this was done.
- Separate analyses seemed to have been conducted for AstraZeneca and Pfizer-BioNTech but it is unclear how the study subjects for each analysis were assigned.

2. Lopez Bernal et al., Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. medRxiv. **Preprint** March 2, 2021. https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

Description: Test negative-case control study using linked surveillance data in the United Kingdom among patients ≥70 years of age. PCR tests were within 10 days of onset of symptoms. For those who were vaccinated, cases and controls were assessed by time since vaccination to onset of symptoms, controlling for a number of factors. The impact of vaccination on hospitalization in individuals ≥80 years of age was also assessed in those who tested positive.

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Results: One-dose vaccine effectiveness against symptomatic PCR confirmed SARS-CoV-2 infection in the adjusted analysis was 22% (95% CI: 11 – 32) 14 to 20 days after vaccination and gradually rose up to 73% (95% CI: 27 – 90) 35 or more days (maximum 48 days) after vaccination. As well as the effect against symptomatic disease, in individuals who were ≥80 years of age there was an additional 37% protection against hospitalization within 14 days of a positive test in those 14 or more days from their first dose of vaccine compared to those who were unvaccinated.

Review:

- Record linkage using large data sets is a strength of this study.
- A relatively small number of subjects were included in the AstraZeneca COVID-19 vaccine analysis at later time periods, particularly in the time period of 35 or more days after vaccination when the vaccine effectiveness was the highest.
- The unadjusted and adjusted odds ratio are considerably different in the AstraZeneca COVID-19 analysis reflecting differences between study groups.
- Demographic and clinical information for cases and controls and vaccinated and unvaccinated individuals were not provided.

3. Vasileiou et al. Effectiveness of first dose COVID-19 vaccines against hospital admissions in Scotland effectiveness findings from Scotland: national prospective cohort study of 5.4 million people. SSRN-Lancet **preprint.** February 19, 2021. https://papers.ssm.com/sol3/papers.cfm?abstract_id=3789264

Description: A prospective observational cohort study using record linkage between databases, including vaccination, hospitalization and laboratory records for the population in Scotland, with adjustment for a number of factors. Although the study included those ≥18 years of age, the AstraZeneca vaccine was mostly administered to participants aged 65 years and older. Age-specific vaccine effectiveness is provided but did not distinguish between the Pfizer-BioNTech and AstraZeneca vaccines, which were both studied, although those ≥80 years of age mainly received the AstraZeneca vaccine.

Results: The effectiveness of one dose of the AstraZeneca vaccine against hospitalization was 74% (95% CI: 66 – 81) 14 to 20 days after vaccination and rose up to 94% (95% CI: 73 – 99) 28 to 34 days after vaccination. In patients ≥80 years of age, the authors found a peak vaccine effectiveness (VE) of 81% (95% CI: 65 – 90) against hospitalization within 28 to 34 days after one dose of vaccine that was mainly the AstraZeneca vaccine.

Review:

Due to concerns with methodological weaknesses in this study, NACI did not use these results to inform its recommendations. Methodological weaknesses include:

- AstraZeneca COVID-19 vaccine effectiveness against hospitalization was high (70%) 7 to 13 days after vaccination, which is biologically implausible, as 7 to 13 days would be too early to expect protection from infection or hospitalization as a result of vaccination, suggesting methodological concerns and making the high vaccine effectiveness results at later time periods (94% at 28 to 34 days) challenging to interpret.
- The number of people vaccinated with the AstraZeneca COVID-19 vaccine is small in the period 28 days and more from vaccination.
- As vaccine roll out was initially tailored to priority groups at higher risk of severe disease or exposure, adjustments for potential confounding factors conducted during the

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statistical analyses might not have adequately controlled for all the differences between vaccinated and unvaccinated individuals. Demographic and risk factor comparisons between vaccinated and unvaccinated groups were not provided separately for each vaccine.

- Hospital admission was defined as: COVID-19 as the main cause of admission or hospitalization within 28 days of a positive PCR SARS-CoV-2 test. Hospital admission for COVID-19 is a less specific criteria for determining COVID-19 hospitalization and the proportion of cases defined using that criteria are not provided.
- Although product specific vaccine effectiveness and age specific vaccine effectiveness are both provided separately, product specific vaccine effectiveness by age was not provided.
- Record linkage using large data sets is a strength of this study.

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APPENDIX D: CLINICAL TRIAL EVIDENCE SUMMARY FOR JANSSEN COVID-19 VACCINE

Data from Phase 1, 2, and 3 trials were available at the time of authorization for the Janssen vaccine. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. The Phase 3 trial involved 44,325 study participants randomized (1:1) to receive either the vaccine (1 dose of 5×10^{10} viral particles) or placebo. The data presented below was a median of two months after the completion of the series (one dose). Evidence from post-marketing surveillance and studies is found in the main body of this statement.

Efficacy

Symptomatic COVID-19 disease
Estimates of efficacy against moderate to severe/critical COVID-19 disease was the primary outcome for the Phase 3 trial. Due to the relatively broad definition of moderate COVID-19 disease adopted for the clinical trial, less than 1% of identified cases met the mild COVID-19 case definition. Therefore, nearly all observed symptomatic COVID-19 cases are captured by the definition of moderate to severe/critical COVID-19.

The co-primary endpoints for the efficacy analysis of the vaccine are the prevention of the first occurrence of confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 post-vaccination and with onset ≥28 days post-vaccination. The primary analysis is supported by subgroup analyses of the primary endpoints stratified by study country, age group, the presence of comorbidities associated with an increased risk of progression to severe COVID-19 disease, sex, and by race/ethnicity. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 and ≥28 days post-vaccination are secondary endpoints, also supported by analyses stratified by the same subgroups as the primary endpoint. Additional analyses of efficacy in cases with severe/critical COVID-19 include examinations by cases requiring medical intervention, hospitalizations and deaths. For both the primary and secondary endpoints, cumulative incidence curves are used to examine the potential onset and duration of vaccine efficacy. Exploratory analyses of vaccine efficacy against asymptomatic or undetected SARS-CoV-2 infection, symptom severity and viral load are also investigated. Select outcomes from these analyses are presented in this Appendix.

A number of the analyses are conducted in the full analysis set, defined as study participants who were randomized and received the study intervention (vaccine or placebo), regardless of the occurrence of protocol deviations or serostatus at baseline. However, most primary efficacy analyses are conducted in the per-protocol set, defined as study participants who were randomized, received the study intervention (vaccine or placebo), were seronegative at the time of vaccination, and had no major protocol deviations that were judged to possibly impact the efficacy of the vaccine. Many of the subgroup analyses are conducted in the per-protocol set using centrally confirmed COVID-19 cases, but repeated using a larger dataset consisting of both centrally confirmed cases and cases with a positive PCR result from a local testing site that had not yet been confirmed by the central clinical trial testing facility at the date of data cut-off for the analysis. The use of the locally confirmed cases is supported by the demonstration of a high concordance (90.3%) in PCR results between local and central clinical trial testing facilities. **Unless otherwise specified, all efficacy analyses presented in this summary are**

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in the per-protocol set of study participants based on a January 22, 2021 data cut-off date.

Confirmed symptomatic moderate to severe/critical COVID-19 infection

The definition of moderate COVID-19 disease used in the clinical trial was very broad and so cases meeting the moderate to severe/critical case definition constituted >99% of all identified symptomatic COVID-19 in the trial. The estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onsets ≥14 days and ≥28 days post-vaccination are 66.9% and 66.1%, respectively (Table 15).

Table 15. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, per-protocol set

Co-Primary outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
Moderate and severe/critical COVID-19 infection	116/19,514	3,116.6	348/19,544	3,096.1	66.9% (59.0 to 73.4)
≥28 days post-vaccination					
Moderate and severe/critical COVID-19 infection	66/19,306	3,102.0	193/19,178	3,070.7	66.1% (55.0 to 74.8)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Tables 5 and 6

Confirmed symptomatic severe/critical COVID-19 infection

The estimates of vaccine efficacy against confirmed symptomatic severe/critical COVID-19 infection are 76.7% with onset ≥14 days post-vaccination and 85.4% with onset ≥28 days post-vaccination (Table 16).

Table 16. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, per-protocol set

Co-Primary outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
Severe/critical COVID-19 infection	14/19,514	3,125.1	60/19,544	3,122.0	76.7% (54.6 to 89.1)
≥28 days post-vaccination					
Severe/critical COVID-19 infection	5/19,306	3,106.2	34/19,178	3,082.6	85.4% (54.2 to 96.9)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Tables 5 and 6

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Subgroup analyses

By study country

The time period of the clinical trial was associated with the emergence of new SARS-CoV-2 VOC in some study countries. At the time of data cut-off for the primary analysis, preliminary genetic sequencing data were available for a proportion of case isolates from Brazil, South Africa and the US (Table 17). No SARS-CoV-2 variants from the B.1.1.7 (Alpha) or P.1 (Gamma) lineages were detected in any of the sequenced isolates.

Table 17. Genetic sequencing results for VOC, September–December, 2020

Country	Cases identified N	Cases sequenced n (%)	Sequencing Results
Brazil	179	124 (69.2)	86/124 (69.4%) – variant 20J/501Y.V3 of the of the P.2 (Zeta) lineage 38/124 (30.6%) – Wuhan-Hu1 reference sequence+D614G
South Africa	136	91 (66.9)	86/91 (94.5%) – variant 20H/501Y.V2 of the B.1.351 (Beta) lineage
United States	268	197 (73.5)	190/197 (96.4%) – Wuhan-Hu1 reference sequence+D614G

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Section 4.1.3.1. Epidemiologic Setting of the Study

Analyses of vaccine efficacy by country were conducted in countries with >100 identified cases (US, 247; Brazil, 153; and South Africa, 133) using a dataset consisting of both centrally PCR-confirmed COVID-19 cases and cases with a positive PCR result from in-country testing not yet confirmed by the central clinical trial testing facility at the data cut-off date for the analysis. The rationale for inclusion of the locally confirmed cases was demonstration of a high concordance (90.3%) in PCR results between local and central clinical trial testing facilities. The point estimates of vaccine efficacy by country against both confirmed symptomatic moderate to severe/critical COVID-19 and severe/critical COVID-19 with onset ≥14 days and ≥28 days post-vaccination are comparable to or greater than the overall estimates of efficacy at these time points (Table 18). The one exception is the point estimate of efficacy for South Africa at ≥14 days post-vaccination.

Table 18. Efficacy against confirmed symptomatic moderate to severe/critical and severe/critical COVID-19, by country for countries with greater than 100 moderate to severe/critical cases, centrally and in-country PCR-confirmed cases

Country	Onset post-vaccination	COVID-19 severity	
		Moderate to severe/critical Efficacy (95% CI)	Severe/critical Efficacy (95% CI)
US	≥14 days	74.4% (65.0 to 81.6)	78.0% (33.1 to 94.6)
	≥28 days	72.0% (58.2 to 81.7)	85.9% (-9.4 to 99.7)
Brazil	≥14 days	66.2% (51.0 to 77.1)	81.9% (17.0 to 98.1)
	≥28 days	68.1% (48.8 to 80.7)	87.6% (7.8 to 99.7)
South Africa	≥14 days	52.0% (30.3 to 67.4)	73.1% (40.0 to 89.4)
	≥28 days	64.0% (41.2 to 78.7)	81.7% (46.2 to 95.4)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 11

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By age group

Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination was assessed in a variety of age groups (Table 19).

Table 19. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by age group, per-protocol set

Age group (years)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
18–39	47/4,356	775.3	122/4,330	762.1	62.1% (46.6 to 73.6)
40–59	48/8,394	1,331.5	138/8,452	1,332.9	65.2% (51.3 to 75.5)
60–69	19/4,800	722.9	65/4,907	732.2	70.4% (50.0 to 83.2)
70–79	2/1,768	259.5	23/1,650	239.2	92.0% (67.6 to 99.1)
≥80	0/196	27.42	0/205	29.8	N/A*
<60 (i.e., 18–59)	95/12,750	2,106.8	260/12,782	2,095.0	63.7% (53.9 to 71.6)
<65 (i.e., 18–64)	107/15,544	2,530.3	297/15,552	2,511.2	64.2% (55.3 to 71.6)
≥60	21/6,764	1,009.8	88/6,762	1,001.2	76.3% (61.6 to 86.0)
≥65	9/3,970	586.3	51/3,992	584.9	82.4% (63.9 to 92.4)
≥75	0/751	88.4	8/690	99.2	100.0% (45.9 to 100.0)
≥28 days post-vaccination					
18–39	29/4,316	772.4	84/4,254	756.6	66.2% (47.9 to 78.6)
40–59	23/8,301	1,325.2	68/8,273	1,320.4	66.3% (45.2 to 80.0)
60–69	12/4,749	719.3	32/4,833	727.1	62.1% (24.4 to 82.2)
70–79	2/1,746	257.8	9/1,620	237.2	79.6% (1.2 to 97.9)
≥80	0/194	27.3	0/198	29.3	N/A
<60 (i.e., 18–59)	52/12,617	2,097.6	152/12,527	2,077.0	66.1% (53.3 to 75.8)
<65 (i.e., 18–64)	60/15,378	2,518.7	170/15,253	2,490.1	65.1% (52.9 to 74.5)
≥60	14/6,689	1,004.4	41/6,651	993.6	66.2% (36.7 to 83.0)
≥65	6/3,928	583.3	23/3,925	580.5	74.0% (34.4 to 91.4)
≥75	0/740	106.4	3/673	98.1	N/A

*N/A = Not available; estimates of vaccine efficacy not calculated when there were fewer than 6 events identified.
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 30 and 31

The efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination was calculated for four age groups: 18–59, 18–64, ≥60, and ≥65 years of age (Table 20).

The analysis was repeated using the larger dataset of both confirmed COVID-19 cases and cases with a positive PCR result from a local, in-country testing site. The estimates of vaccine efficacy in participants ≥65 years of age at ≥14 days and ≥28 days post-vaccination increased to 71.4% and 70.1%, respectively.

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Table 20. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by age group, per-protocol set

Age group (years)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
18–59	8/12,750	2,114.3	41/12,782	2,115.1	80.5% (57.8 to 92.1)
18–64	11/15,544	2,538.5	50/15,552	2,533.8	78.0% (57.3 to 89.7)
≥60	6/6,764	1,010.7	19/6,762	1,006.9	68.5% (18.1 to 89.7)
≥65	3/3,970	586.6	10/3,992	588.3	69.9% (-16.8 to 94.7)
≥28 days post-vaccination					
18–59	2/12,617	2,101.0	24/12,527	2,086.7	91.7% (66.7 to 99.1)
18–64	2/15,378	2,522.8	28/15,253	2,500.9	92.9% (71.9 to 99.2)
≥60	3/6,689	1,005.1	10/6,651	995.9	70.3% (-15.5 to 94.7)
≥65	3/3,928	583.4	6/3,925	581.7	50.1% (-133.4 to 91.9)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 32 and 33

By comorbidity

In the clinical trial, the presence of comorbidities was defined as a study participant with one or more medical conditions at baseline that were associated with an increased risk of progression to severe COVID-19 disease (e.g., asthma, cerebrovascular disease, hypertension, respiratory disease, liver disease, and obesity). In participants with and without comorbidities, efficacy was assessed against confirmed symptomatic moderate to severe/critical and against severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination (Table 21).

A repeat of the analysis using the larger dataset of both centrally and locally in-country confirmed COVID-19 cases estimated vaccine efficacy against (a) moderate to severe/critical COVID-19 infection and (b) against severe/critical COVID-19 infection in participants with comorbidities of 58.6% (95% CI: 40.6 to 71.6%) and 75.2% (95% CI: 32.0 to 92.7%) with onset ≥28 days post-vaccination.

Table 21. Efficacy against confirmed symptomatic (a) moderate to severe/critical and (b) severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by presence or absence of comorbidities, per-protocol set

Presence of comorbidities (yes/no)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
(a) Moderate to severe/critical COVID-19 infection					
≥14 days post-vaccination					
Yes	47/7,777	1,140.0	126/7,798	1,133.7	62.9% (47.8 to 74.1)
No	69/11,737	1976.6	222/11,746	1,962.5	69.1% (59.4 to 76.8)
≥28 days post-vaccination					
Yes	27/7,684	1,133.6	52/7,626	1,121.7	48.6% (16.7 to 69.0)
No	39/11,622	1,968.4	141/11,552	1,949.0	72.6% (60.7 to 81.3)
(b) Severe/critical COVID-19 infection					
≥14 days post-vaccination					
Yes	8/7,777	1,142.9	29/7,798	1,141.7	72.4% (38.2 to 89.1)
No	6/11,737	1,982.1	31/11,746	1,980.3	80.7% (53.0 to 93.4)
≥28 days post-vaccination					
Yes	4/7,684	1,135.0	12/7,626	1,124.2	67.0% (-8.9 to 92.2)
No	1/11,622	1,971.1	22/11,552	1,958.3	95.5% (72.1 to 99.9)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 30, 31, 32 and 33

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By serostatus

This analysis was conducted using the expanded dataset of both centrally and locally confirmed COVID-19 cases and estimated vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection in study participants based on serostatus at baseline (Table 22).

Table 22. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, including confirmed and non-centrally confirmed cases, by serostatus, per-protocol set

Baseline SARS-CoV-2 serostatus	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
Regardless of baseline status	176/21,636	3,450.2	513/21,574	3,409.8	66.1% (59.7 to 71.6%)
Positive	3/2,122	336.3	4/2,030	320.8	28.5% (-322.8 to 89.5)
Negative	173/19,514	3,113.9	509/19,544	3,089.1	66.3% (59.9 to 71.8)
≥28 days post-vaccination					
Regardless of baseline status	114/21,424	3,436.3	326/21,199	3,385.9	65.5% (57.2 to 72.4)
Positive	1/2,118	336.1	2/2,021	320.0	N/A*
Negative	113/19,306	3,100.3	324/19,178	3,065.9	65.5% (57.2 to 72.4)

*N/A = Not available; estimates of vaccine efficacy not calculated when there were fewer than 6 events identified.
Source: Table 14, FDA Briefing document for Vaccines and Related Biological Products Advisory Committee meeting (February 26, 2021)

Hospitalizations

A post-hoc analysis assessed vaccine efficacy against COVID-19 associated hospitalizations. The analysis was performed for cases with onset ≥1 day, ≥14 days and ≥28 days post-vaccination in study participants seronegative at baseline (Table 23). At each time point, the analysis was performed using (a) centrally confirmed COVID-19 cases only, and (b) both centrally and locally confirmed cases ("Any positive PCR result").

Table 23. Efficacy against COVID-19 associated hospitalizations with onset ≥1, ≥14 and ≥28 days post-vaccination

Analysis population	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥1 day post-vaccination (in FAS-SN)					
Confirmed cases	6	3,202.8	18	3,213.1	66.6% (12.1 to 89.1)
Any positive PCR result	6	3,202.8	42	3,211.6	85.7% (66.1 to 95.0)
≥14 days post-vaccination (PP)					
Confirmed cases	2	3,125.8	11	3,125.9	81.8% (16.7 to 98.0)
Any positive PCR result	2	3,125.8	29	3,125.1	93.1% (72.7 to 99.2)
≥28 days post-vaccination (PP)					
Confirmed cases	0	3,106.3	6	3,084.4	100.0% (15.7 to 100.0)
Any positive PCR result	0	3,106.3	16	3,083.9	100.0% (74.3 to 100.0)

FAS-SN = Full analysis set, all randomized study participants with documented study vaccine administration, seronegative at baseline; PP = per-protocol set
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 10

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Deaths

There were 19 deaths reported during the clinical trial: 3 in the vaccine group and 16 in the placebo group. Of the 19 deaths, zero in the vaccine group were determined to be associated with COVID-19, based on WHO COVID-19 case classifications combined with a positive RT-PCR result, compared to 5 COVID-19 associated deaths in the placebo group. All 5 deaths in the placebo group were in South African study participants with one or more comorbidities with an increased risk for progression to severe COVID-19 disease.

Asymptomatic or undetected SARS-CoV-2 infection

Analysis of vaccine efficacy against asymptomatic or undetected COVID-19 infection (study participants not meeting one of the case definitions for symptomatic COVID-19 and with a positive PCR or serology result) and against seroconversion were conducted at two time points: with onset 1 to 29 days and ≥28 days post-vaccination. A sensitivity analysis was also performed for each of these outcomes by removing participants with symptoms at any time since screening and prior to the positive PCR or serology result ("without previous symptoms").

The point estimate of vaccine efficacy against asymptomatic or undetected COVID-19 infection with onset ≥28 days post-vaccination is 59.7% (and 74.0% after removal of participants with prior symptoms) and against seroconversion it is 66.5% (74.2% with removal of participants with prior symptoms) (Table 24). The seroconversion results should be interpreted with caution as this is a preliminary analysis based on a limited duration of follow-up in approximately 29% of study participants planned for the final analysis based on Day 71 serology.

Table 24. Efficacy against asymptomatic and undetected COVID-19 infection, and against seroconversion, with onset ≥28 days post-vaccination

Outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
Full analysis set, seronegative at baseline					
Asymptomatic or undetected SARS-CoV-2 infection	22/19,301	3,099.7	54/19,162	3,064.2	59.7% (32.8 to 76.6)
Asymptomatic or undetected SARS-CoV-2 infection *without previous symptoms*	10/19,301	3,098.0	38/19,162	3,061.5	74.0% (46.8 to 88.4)
Serology risk set*					
Seroconverted	18/1,346	312.2	50/1,304	298.2	65.5% (39.9 to 81.1)
Seroconverted *without previous symptoms*	10/1,346	310.9	37/1,304	296.6	74.2% (47.1 to 88.6)

*Serology risk set = study participants with a serology result available at Day 71 post-vaccination
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 12

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Immunogenicity

The majority of the immunogenicity analysis is based on data from a Phase 1 trial that included 2 cohorts of healthy adults aged 18 to 55 and ≥65 years of age. Within each cohort, there were two dose levels given as one or two doses. The analysis below is from one dose of the lower dose, $5x10^{10}$ viral particles.

Humoral immune responses
Antibody responses were elicited by one dose of the Janssen vaccine. Binding and neutralizing antibodies reached a maximum by day 29 and maintained through day 85 (last time point of evaluation) in the younger cohort. In the older cohort, binding antibody responses were slightly lower than those in the younger cohort and were elicited more slowly, increasing from day 15 through day 57 (last time point of evaluation). Neutralizing antibody responses were similar levels to those in the younger cohort, elicited by day 15 and maintained an approximate plateau through day 57. Functional antibody responses as determined through Fc effector function were maximally elicited by day 29 (the last day of evaluation), at similar levels in both age cohorts.

Minimal data are available for seropositive vaccine recipients that may suggest that they respond strongly to one dose of vaccine.

Minimal data are also available demonstrating decreased neutralizing antibody responses to viral variant B.1.1.7 (Alpha).

Without a correlate of protection, the significance of these difference in antibody responses is unclear.

Cellular immune responses
Cellular immune responses were elicited by one dose of this vaccine and were similar in both age cohorts. Spike protein-specific CD4+ T cells responses were detected in 76% of younger vaccine recipients and 60% of older vaccine recipients. Th-1 biased CD4+ T cell responses were observed by day 15 post-vaccination and remained elevated until day 29 (last time point of evaluation). Spike protein-specific CD8+ T cells responses were detected in 51% of younger vaccine recipients and 36% of older vaccine recipients by day 15 post vaccination and remained elevated until day 29.

Anti-vector immune responses
It is unclear to what extent pre-existing immunity to any adenovirus-based vaccine vector exists in the Canadian population and what impact that could have on adenovirus based vaccine safety and efficacy. It is also unclear as to what extent immunization with adenovirus-based vaccines elicits anti-vector immune responses and what impact that could have on homologous or heterologous booster doses with adenovirus-based vaccines. Evidence for a COVID-19 viral vector vaccine based on human adenovirus 5 (not authorized in Canada) indicated that vaccine recipients with high pre-existing immunity to the adenovirus vector had lower anti-SARS-CoV-2 immune responses [144]. The Janssen COVID-19 vaccine uses a modified Ad26. Janssen found no correlation between anti-Ad26 neutralizing antibody responses and anti-SARS-CoV-2 immune responses. However, neutralization is not the only anti-vector immune response that could impact vaccine-induced immunity. It remains unclear if immune responses to the Ad26 vector will impact the efficacy or effectiveness of this vaccine.

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Vaccine safety and adverse events following immunization

Safety evidence is based on interim analyses of 21,895 participants (of whom 7,331 were ≥60 years of age) who received at least one dose of the vaccine. A safety subset included 3,356 participants in the vaccine group who were followed for solicited reactions within 7 days following vaccination and unsolicited reactions within 28 days following vaccination. Medically attended adverse events (MAAEs), SAEs and AEs leading to discontinuation from study participation were assessed in all participants. Overall, the median duration of follow-up was 58 days after vaccination.

Solicited local reactions

Solicited local injection site AEs were reported by 50.3% of evaluated participants within the first 7 days following any vaccine dose. Injection site pain was the most frequently reported local AE (48.7%) followed by warmth (7.3%) and swelling (5.3%). In the vaccine group, the frequency of solicited local AEs was lower in participants aged ≥60 years compared to participants aged ≥18 to <60 years. The frequency of solicited local AEs was also similar in participants who were seronegative for SARS-CoV-2 at baseline compared to participants who were seropositive for SARS-CoV-2 at baseline (50.1% and 54.5%, respectively). The majority of solicited local reactions among vaccine recipients were mild or moderate in severity, with any Grade 3 reactions being reported by ≤0.7% of participants. No Grade 4 solicited local AEs were reported.

Solicited systemic reactions

Solicited systemic AEs were reported by 55.2% of evaluated participants within the first 7 days following vaccine administration. The most common systemic solicited AEs were headache (39.0%) and fatigue (38.3%). Other frequently reported systemic solicited AEs were muscle pain (33.2%), nausea (14.2%) and fever ≥38.0°C (9.0%). While AEs were lower in participants aged ≥60 years compared to participants aged ≥18 to <60 years, there were no clinically relevant differences in the frequency of solicited systemic AEs. AEs were similarly observed in participants who were seronegative for SARS-CoV-2 at baseline (55.4%) compared to participants who were seropositive for SARS-CoV-2 at baseline (50.6%). Overall, the frequency of any Grade 3 reactions was <2%, and no Grade 4 solicited systemic AEs were reported. Antipyretics were recommended post-vaccination for symptom relief as needed. Analgesics or antipyretics were used by 26.4% of vaccinated 18 to 59 year olds and 9.8% of vaccinated individuals 60 years of age and older up to 7 days post vaccination in the full analysis. The majority of solicited systemic AEs were transient in nature and had a median duration of 1 to 2 days after vaccination.

Unsolicited serious adverse events

During the 28-day period post-vaccination, there were 19 (0.6%) participants with unsolicited AEs of at least Grade 3 in the vaccine group compared to 18 (0.6%) participants in the placebo group. Of these unsolicited AEs of at least Grade 3, 5 (0.1%) were considered to be related to the study vaccine. There were no clear imbalances by System Organ Class (SOC). No cases of anaphylaxis were identified in the clinical trials. However, the manufacturer announced receipt of preliminary reports of two cases of severe allergic reactions, including one case of anaphylaxis, in participants who had received the vaccine. Details on the reports have not been provided to date.

In total there were 7 (<0.1%) participants who reported SAEs that were considered to be related to the study vaccine by the investigator and lead to discontinuation from the study. These included:

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- Grade 4 Guillain-Barré syndrome in a participant 16 days after vaccination. The case was considered indeterminate as per WHO AEFI criteria; however, due to close temporal association and lack of other explanatory factors, it was considered as possibly related to the vaccine for reporting purposes.
- Grade 4 pericarditis in a participant approximately 17 days following vaccination and resulted in hospitalization. The event was assessed as indeterminate as per WHO AEFI criteria; however, due to close temporal association and a lack of other explanatory factors it was assessed as possibly related to the vaccine for reporting purposes.
- Grade 3 brachial radiculitis in a participant with immediate onset following vaccination.
- Grade 3 post-vaccination syndrome 2 days following vaccination. Based on the symptoms, the event was assessed as vaccine reactogenicity (asthenia).
- Grade 3 Type IV hypersensitivity in a participant 3 days following vaccination. The case was considered likely related to vaccination due to close temporal association.
- Grade 2 facial paralysis (Bell's Palsy) in two participants 3 and 16 days after vaccination. Both events were assessed to have an inconsistent causal association with immunization, per the WHO AEFI criteria.

Other serious adverse events

Tinnitus

Six cases of tinnitus were reported in the vaccine group and none in the placebo group. All cases were considered non-serious, and two cases were considered related by the investigator. All participants had underlying medical conditions (such as history of tinnitus and migraine, history of hypertension, seasonal allergies and hypothyroidism) or used medications that offered a more plausible alternative cause for the event compared to the vaccine.

Convulsions/seizures

Four cases were reported in the vaccine group (1 serious) and one case (non-serious) in the placebo group, all of which were considered not related to the study vaccine by the investigator. The serious case of convulsion/seizure was reported in a participant with a history of epilepsy and obsessive-compulsive disorder.

Thrombotic and thromboembolic events

The overall incidence of thrombotic and thromboembolic events (arterial and venous) was similar across the vaccine (n=15, 0.1%) and placebo groups (n=10, <0.1%). A numerical imbalance was observed for the deep vein thrombosis deep/ pulmonary embolism subtypes, with a total of 9 cases in the vaccine group (4 serious) and 3 cases in the placebo group (2 serious). One case of transverse sinus thrombosis occurred on Day 21 following vaccination in a 25-year-old male participant with no past medical history. The participant also presented a seizure reported to be a consequence of a secondary bleed caused by elevated venous pressure from the venous flow obstruction. Two thrombectomy procedures were performed because of the participant's hypercoagulable state. No clear cause of the event was identified and it was deemed unrelated to the vaccine as there were possible contributing factors (preceding infection and anatomical anomaly). One non-serious case with onset 27 days after vaccination in a participant with a medical history of obesity and cholecystectomy was considered to be related to the vaccine.

Vaccine-Induced Immune Thrombotic Thrombocytopenia

Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported in the United States following post-licensure use

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of Janssen COVID-19 vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and has been associated with both the AstraZeneca and Janssen COVID-19 viral vector vaccines. The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the viral vector COVID-19 vaccines may trigger VITT is still under investigation. As of May 24, 2021, 32 cases of TTS out of about 10.2 million doses of Janssen administered in the United States have been confirmed. Most of the cases to date have occurred in females between the ages of 18 and 49 years; however, investigations are ongoing and additional cases may be identified with increased awareness and current emphasis on the clinical recognition of this event. Reports indicated symptom onset between 6 and 15 days after vaccination. Investigations are ongoing.

Demyelinating disorders

In total there were four cases of demyelinating disorders that were reported in the vaccine group (2 cases peripheral neuropathy, 1 benign monoclonal hypergammaglobulinemia, 1 Guillain-Barré syndrome) compared with 5 cases in the placebo group (2 cases peripheral neuropathy, 1 Guillain-Barré syndrome and 2 sensory loss.

Death

A total of 19 deaths were reported among study participants (3 in the vaccine group and 16 in the control group). In the vaccine group, causes of death by preferred term were lung abscess, non-COVID-19 pneumonia, and 1 of unknown cause at the time of data cut-off. None of these deaths were considered to be related to the study intervention by the investigators.

Pregnancies

Eight pregnancies were reported through January 22, 2021 (4 vaccine, 4 placebo). Vaccination was within 30 days after last menstrual period in 7 participants (3 vaccine, 4 placebo) while in 1 vaccine recipient vaccination was prior to last menstrual period. Unsolicited AEs related to pregnancy included spontaneous abortion (1 vaccine, 0 placebo), incomplete abortion (0 vaccine, 1 placebo), elective abortion (0 vaccine, 2 placebo) and ectopic pregnancy (1 vaccine, 0 placebo). Two pregnancies are ongoing among participants in the vaccine group, with unknown outcomes at this time.

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APPENDIX E: FREQUENCY OF SOLICITED ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 VACCINES IN CLINICAL TRIALS

Table 25. Frequency of solicited local adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine								Moderna COVID-19 Vaccine			
	Adults (≥16 years old)				Adolescents (12 -15 years old)							
	Vaccine		Placebo control		Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Redness/erythema	Common	Common	Common	Rare	Common	Common	Common	Uncommon	Common	Common	Uncommon	Uncommon
Swelling	Common	Common	Rare	Rare	Common	Common	Common	Uncommon	Common	Very Common	Uncommon	Uncommon
Lymphadenopathy[b]/ Axillary swelling and tenderness	NS	NS	NS	NS	NS	NS	NS	NS	Very Common	Very Common	Common	Common
Warmth	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Pruritis	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Induration	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Lymphadenopathy was not a solicited adverse event for the Pfizer BioNTech COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix A for more details.

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Table 26. Frequency of solicited local adverse events in authorized populations for viral vector COVID-19 vaccines[a]

AEFI	AstraZeneca COVID-19 Vaccine				Janssen COVID-19 Vaccine[b]	
	Vaccine		MenACWY control		Vaccine	Placebo control
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	Very Common	Very Common	Very Common	Very Common	NS	NS
Redness/erythema	Very Common	Common	Common	Uncommon	Common	Common
Swelling	Common	Common	Common	Common	Common	Common
Lymphadenopathy[c]/ Axillary swelling and tenderness	NS	NS	NS	NS	NS	NS
Warmth	Very Common	Common	Very Common	Common	NS	NS
Pruritis	Very Common	Common	Common	Common	NS	NS
Induration	Common	Common	Common	Common	NS	NS

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Single dose vaccine (dose 2 not applicable)

[c] Lymphadenopathy was not a solicited adverse event for the AstraZeneca or Janssen COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix C for more details.

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Table 27. Frequency of solicited systemic adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine								Moderna COVID-19 Vaccine			
	Adults (≥16 years old)				Adolescents (12 -15 years old)							
	Vaccine		Placebo control		Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Very Common	Common	Common	Very Common	Very Common	Common	Common	Common	Very Common	Common	Common
Joint Pain	Common	Very Common	Common	Common	Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Very Common
Fever[b]	Common	Very Common	Uncommon	Uncommon	Very Common	Very Common	Common	Uncommon	Uncommon	Very Common	Uncommon	Uncommon
Feverishness[b]	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Diarrhea	Common	Common	Common	Common	Common	Common	Common	Common	NS	NS	NS	NS
Nausea and/or Vomiting[c]	Uncommon	Common	Uncommon	Uncommon	Common	Common	Uncommon	Common	Common	Very Common	Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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Table 28. Frequency of solicited systemic adverse events in authorized populations for viral vector COVID-19 vaccines[a]

AEFI	AstraZeneca COVID-19 Vaccine				Janssen COVID-19 Vaccine[b]	
	Vaccine		MenACWY control		Vaccine	Placebo control
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Common	Common	Common	NS	NS
Joint Pain	Very Common	Very Common	Common	Common	NS	NS
Fever[c]	Common	Common	Uncommon	Uncommon	Common	Uncommon
Feverishness[c]	Very Common	Common	Common	Common	NS	NS
Diarrhea	NS	NS	NS	NS	NS	NS
Nausea and/or Vomiting[d]	Very Common/ Common	Common/ Uncommon	Very Common/ Uncommon	Common/ Uncommon	Very Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Single dose vaccine (dose 2 not applicable)

[c] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[d] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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APPENDIX F: PREGNANCY, BREASTFEEDING AND COVID-19 VACCINE REGISTRIES

There is a Canadian COVID-19 vaccine registry for pregnant and breastfeeding individuals:

- Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals

Table 29: Pregnancy registry information by vaccine product

Vaccine product	Registry information
Pfizer-BioNTech COVID-19 vaccine	Pfizer does not have a pregnancy exposure registry. Pfizer COVID-19 vaccine recipients and health care providers are encouraged to report any exposure to COVID-19 vaccine during pregnancy or breastfeeding to the vaccine manufacturer (1-866-723-7111).
Moderna COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the Moderna COVID-19 vaccine during pregnancy. Women who are vaccinated with the Moderna COVID-19 vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866- 663-3762).
AstraZeneca COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AstraZeneca COVID-19 vaccine during pregnancy. Women who are vaccinated with AstraZeneca COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com or calling 1-800-616-3791.
Janssen COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com

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SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) UPDATES OF JULY 2, 2021

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JULY 2, 2021

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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MRNA COVID-19 VACCINES AND MYOCARDITIS

- On July 2, 2021, the Public Health Agency of Canada released updated advice from the National Advisory Committee on Immunization (NACI) on the use of mRNA COVID-19 vaccines. These recommendations are based on current scientific evidence and NACI's expert opinion.

- On June 30, 2021, Health Canada updated the product monographs, the documents that provide information for health care providers on the use of the vaccines, for the mRNA COVID-19 vaccines (Pfizer-BioNTech, Moderna) to include very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.

- In light of these changes, NACI is providing updated advice on second doses for individuals who experienced myocarditis and/or pericarditis after receiving a first dose of an mRNA vaccine.

- NACI continues to strongly recommend that a complete series with an mRNA vaccine should be offered to all eligible individuals without contraindications, including those 12 years of age and older. The Pfizer-BioNTech vaccine is approved for use in people 12 years and over and the Moderna vaccine is approved for use in people 18 years of age and over.

NACI is now also recommending the following:

- Informed consent for people receiving an mRNA vaccine should include a discussion about the very rare risk of myocarditis and/or pericarditis following immunization.

- As a precaution, NACI recommends that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA vaccine should wait to get their second dose until more information is available.

To see the full update, please visit NACI Recommendations on the use of COVID-19 Vaccines.

WHAT YOU NEED TO KNOW

- Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the lining around the heart. There are many potential causes of myocarditis and pericarditis, including viral infections. It can also occur as a complication in people who are infected with SARS-CoV-2, the COVID-19 virus.

- A small number of cases of myocarditis and/or pericarditis following immunization with mRNA COVID-19 vaccines have been reported in Canada and internationally. Internationally, cases have been reported more frequently in adolescents and younger adults under 30 years of age, more often in males than in females, and more frequently

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after a second dose. The majority of cases have been mild and individuals have recovered quickly.

- NACI continues to strongly recommend that a complete series with an mRNA vaccine should be offered to all eligible individuals, including those 12 years of age and older. mRNA COVID-19 vaccines provide very good protection against SARS-CoV-2 infection and symptomatic COVID-19 disease, including severe illness, hospitalization and death.

- People who are offered an mRNA COVID-19 vaccine should be informed of the very rare risk of myocarditis and/or pericarditis following immunization and should be advised to seek immediate medical attention if they develop symptoms, which may include chest pain, shortness of breath, or the feeling of a fast, pounding or fluttering heartbeat. Cases typically occur within a week after the receipt of an mRNA vaccine dose, more commonly after a second dose. Any potential cases should be investigated with medical assessment regardless of timing from vaccination to onset.

- As a precaution, NACI recommends that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine should wait to receive a second dose until more information is available.

- The evidence on this safety signal and investigations into an association between myocarditis and/or pericarditis and the mRNA COVID-19 vaccines continue to evolve. NACI will continue to monitor the evidence and will update recommendations as needed.

QUOTES

"We continue to see risk from COVID-19 in our communities, and although adult vaccine coverage is growing daily, there have been recent outbreaks among adolescents in Canada and internationally. It is important for adolescents to continue getting vaccinated, particularly in the context of the Delta variant emerging in Canada."

"We have been closely monitoring the evolving situation of rare cases of myocarditis or pericarditis following mRNA vaccination among younger people. NACI is encouraged to see that the clinical presentations appear mild, and resolve quickly. The benefits of the COVID-19 immunization program continue to outweigh the relatively small risk for all people including adolescents. It will be important for informed consent to include a discussion about what to watch for after vaccination and to seek medical care if symptoms develop. As a precaution, anyone who experiences myocarditis or pericarditis after the first dose should wait for us to learn more before getting a second dose."

- Dr. Shelley Deeks, NACI Chair

"There have been a small number of cases of myocarditis and pericarditis reported in Canada after vaccination. Evidence is evolving, and Canadian and international investigations into an association between myocarditis/pericarditis and mRNA vaccines continue. I want to let

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Canadians know that the benefits of mRNA COVID-19 vaccines continue to outweigh their potential risks. It is important that everyone gets their second vaccine dose to provide the best protection. The Government of Canada encourages people to get vaccinated and complete their vaccine series as soon as they are eligible."

- Dr. Theresa Tam, Chief Public Health Officer

NACI FORWARD AGENDA

NACI continues to actively review emerging evidence on COVID-19 vaccines. Upcoming recommendation may include new advice on:

- Recommendation on the use of the Moderna mRNA COVID-19 vaccine in adolescents (pending a regulatory decision by Health Canada)
- Optimal number of doses for people who have been previously infected with SARS-CoV-2 (expected in summer 2021)
- Advice for individuals who received a partial or complete COVID-19 vaccine series with a vaccine not authorized in Canada (expected in summer 2021)

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Une déclaration d'un comité consultatif (DCC) Comité consultatif national de l'immunisation (CCNI)

Recommandations sur l'utilisation des vaccins contre la COVID-19

Publié: 2 juillet 2021

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PROTÉGER LES CANADIENS ET LES AIDER À AMÉLIORER LEUR SANTÉ

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PRÉAMBULE

Le Comité consultatif national de l'immunisation (CCNI) et un organisme consultatif externe qui donne à l'Agence de la santé publique du Canada (ASPC) des conseils indépendants, continus et à jour dans le domaine de la médecine, des sciences et de la santé publique liés aux questions de l'ASPC concernant l'immunisation.

En plus de la prise en compte du fardeau associé aux maladies et des caractéristiques vaccinales, l'ASPC a élargi le mandat du CCNI de façon à lui permettre d'inclure l'étude systématique des facteurs liés aux programmes dans la formulation de ses recommandations axées sur des données probantes. Cette initiative devrait aider le CCNI à prendre des décisions en temps opportun en ce qui a trait aux programmes de vaccination financés par les fonds publics à échelle provinciale et territoriale.

Les nouveaux facteurs que le CCNI devra examiner de façon systématique sont les suivants : économie, équité, éthique, acceptabilité et faisabilité. Les déclarations du CCNI ne nécessiteront pas toutes une analyse approfondie de l'ensemble des facteurs programmatiques. Même si l'étude systématique des facteurs liés aux programmes sera effectuée à l'aide d'outils fondés sur des données probantes afin de cerner les problèmes distincts susceptibles d'avoir une incidence sur la prise de décision pour l'élaboration des recommandations, seuls les problèmes distincts considérés comme étant propres au vaccin ou à la maladie pouvant être prévenue par un vaccin seront inclus.

La présente déclaration contient les conseils indépendants et les recommandations du CCNI, qui reposent sur les connaissances scientifiques les plus récentes et diffuse ce document à des fins d'information. Les personnes qui administrent le vaccin devraient également connaître le contenu de la monographie de produit pertinente. Les recommandations d'utilisation et les autres renseignements qui figurent dans le présent document peuvent différer du contenu de la monographie de produit rédigée par le fabricant du vaccin au Canada. Les fabricants ont fait homologuer les vaccins et ont démontré leur innocuité et leur efficacité potentielle lorsqu'ils sont utilisés conformément à la monographie de produit uniquement. Les membres du CCNI et les membres de liaison doivent se conformer à la politique de l'ASPC régissant les conflits d'intérêts, notamment déclarer chaque année les conflits d'intérêts possibles.

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TABLEAU DES MISES À JOUR

Ce document évolutif sera mis à jour au fur et à mesure que l'utilisation des vaccins contre la COVID-19 sera autorisée et que les vaccins seront disponibles au Canada, que les données probantes sur ces vaccins et la COVID-19 évolueront et que le Comité consultatif national de l'immunisation (CCI) modifiera ses recommandations en fonction de ces données. Ce tableau résume les renseignements mis à jour fournis dans la version actuelle de ce document depuis la publication de la dernière version du document du 17 juin 2021.

Une liste complète des modifications apportées à ce document se trouve dans le Tableau des mises à jour : Recommandations sur l'utilisation des vaccins contre la COVID-19. Les versions antérieures complètes de ce document sont archivées et sont disponibles sur la page Comité consultatif national de l'immunisation (CCNI) : Déclarations et publications dans la section sur la COVID-19.

Section	Mise à jour	Date
Vaccins : Évènements indésirables peu fréquents, rares et très rares	La section sur la myocardite et la péricardite après l'administration des vaccins à ARNm a été mise à jour, et une section sur le syndrome de fuite capillaire (SFC) après l'administration du vaccin d'AstraZeneca contre la COVID-19 a été ajoutée.	2021-07-02
Vaccins : Précautions	Une section sur la myocardite et/ou la péricardite après la vaccination à ARNm contre la COVID-19 a été ajoutée. Par mesure de précaution, la deuxième dose de la série de vaccins à ARNm contre la COVID-19 devrait être reportée chez les personnes qui souffrent de myocardite ou de péricardite suivant la première dose d'un vaccin à ARNm contre la COVID-19 jusqu'à ce que de plus amples renseignements soient disponibles. Le CCNI continuera à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.	2021-07-02
Contre-indications	Un antécédent de SFC a été ajouté comme une contre-indication à l'administration du vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD.	2021-07-02
Recommandations	Pour faciliter le consentement aux renseignements, la justification de la recommandation (nº 1) du CCNI sur l'utilisation des vaccins à ARNm comprend désormais des renseignements sur les très rares cas de myocardite et de péricardite après la vaccination à ARNm, notant que les cas ont été signalés le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez	2021-07-02

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Section	Mise à jour	Date
	les hommes que chez les femmes et plus souvent après la deuxième dose.	
Recommandations	La recommandation (nº 11) du CCNI sur l'utilisation du vaccin contre la COVID-19 de Pfizer-BioNTech chez les adolescents a été mise à jour pour inclure des directives sur le consentement éclairé en référence aux très rares cas de myocardite et de péricardite après la vaccination à ARNm comme indiqué ci-dessus.	2021-07-02
Tableau 5. Considérations en matière de vaccination selon les types de vaccins contre la COVID-19 dont l'utilisation est approuvée au Canada	Contenu mis à jour pour refléter les changements apportés aux directives comme indiqué ci-dessus.	2021-07-02

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SOMMAIRE DE L'INFORMATION CONTENUE DANS LA PRÉSENTE DÉCLARATION DU CCNI

Les paragraphes suivants présentent des renseignements clés et actuels sur les vaccins contre la COVID-19 à l'intention des fournisseurs de vaccination. Les données probantes sur la COVID-19 et les vaccins contre cette maladie évoluent. Les données probantes issues des essais cliniques sont limitées en raison de la taille et de la durée du suivi des populations des essais. Toutefois, des essais et études cliniques en conditions réelles sont en cours. Le CCNI continuera à surveiller les données probantes et à mettre à jour ses recommandations si nécessaire. Voir le reste de la Déclaration pour obtenir plus de précisions.

Quoi

Maladie

- La nouvelle maladie à coronavirus 2019 (COVID-19) est causée par le coronavirus du syndrome respiratoire aigu sévère 2 (SRAS-CoV-2).
- Des mutations génétiques du virus SRAS-CoV-2 dont certaines rendent le virus plus infectieux et plus transmissible ont été identifiées (« variants »). Elles pourraient également avoir une incidence sur la gravité de la maladie et sur le niveau de protection offert par les vaccins.
- Tout le monde peut être infecté par le SRAS-CoV-2. Cependant, certaines populations sont plus exposées au virus (p. ex., en raison de leur cadre de vie ou de travail), et d'autres sont à risque accru de maladie sévère et de mort en raison de facteurs biologiques (p. ex., âge avancé, affection préexistante) et sociaux (p. ex., faible statut socio-économique, appartenance à une population racialisée), autant de facteurs qui peuvent se croiser. Les facteurs de risque d'exposition et de maladie sévère peuvent se chevaucher, ce qui augmente encore le risque. Toute combinaison de ces facteurs, ainsi qu'un accès variable aux services de soins de santé, peut avoir des conséquences disproportionnées pour des populations particulières.

Vaccins actuellement autorisés et disponibles
(Vaccin contre la COVID-19 de Pfizer-BioNTech, vaccin contre la COVID-19 de Moderna, vaccin contre la COVID-19 d'AstraZeneca, vaccin contre la COVID-19 de Janssen)

- L'utilisation des vaccins à ARNm (acide ribonucléique messager) est autorisée au Canada chez les personnes âgées de 12 ans et plus (vaccin contre la COVID-19 de Pfizer-BioNTech) ou de 18 ans et plus (vaccin contre la COVID-19 de Moderna).
- L'utilisation des vaccins à vecteur viral non réplicatif est autorisée au Canada pour les personnes âgées de 18 ans et plus (vaccin contre la COVID-19 d'AstraZeneca et vaccin contre la COVID-19 de Janssen).
- Dans les essais cliniques, tous les vaccins contre la COVID-19 sont efficaces à court terme contre la COVID-19 symptomatique et confirmée; d'autres essais sont en cours. Les vaccins contre la COVID-19 à ARNm se sont révélés d'une grande efficacité potentielle (94 % ou plus). Le vaccin contre la COVID-19 d'AstraZeneca a montré une efficacité potentielle moyenne d'environ 62 % chez les 18-64 ans. Chez les adultes de 65 ans et plus qui ont reçu une dose d'AstraZeneca, les données d'observation sur l'efficacité potentielle vaccinale ont révélé une réduction du risque de maladie symptomatique et d'hospitalisation. Le vaccin contre la COVID-19 de Janssen a montré une efficacité potentielle de 67 % contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique, selon des études

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menées en Afrique du Sud et au Brésil tandis que le variant préoccupant (VP) B.1.351 (béta) et le variant d'intérêt (VI) P.2. (zêta) circulaient, respectivement. Actuellement, il y a des données probantes limitées sur la durée de la protection et sur l'efficacité potentielle de ces vaccins pour réduire la transmission du SRAS-CoV-2, mais des études sont en cours. Des indications d'une protection contre l'infection asymptomatique par le SRAS-CoV-2 émergent pour les vaccins à ARNm et de Janssen.

- Des données probantes concernant les degrés de protection différents offerte par les vaccins contre la COVID-19 face aux variants évoluent. À ce jour, les données probantes montrent que les vaccins de Pfizer-BioNTech et d'AstraZeneca offrent une protection contre le VP B.1.1.7 (alpha). Il existe également des données probantes émergentes révélant que les deux vaccins offrent aussi une bonne protection contre l'infection par le VP B.1.617.2 (delta) après la deuxième dose et une bonne protection contre l'hospitalisation après la première dose. Des données probantes montrent également que le vaccin de Janssen offre une certaine protection contre le VP B.1.351 (béta) et contre le VI P.2 (zêta). Le vaccin d'AstraZeneca n'offre pas de protection contre le VP B.1.351 (béta) selon les données probantes actuelles.
- Pour chacun des vaccins, on a déclaré que certains évènements indésirables (ÉI) sollicités étaient très fréquents chez les sujets vaccinés (10 % d'entre eux ou plus). Cependant, ils sont légers ou modérés et transitoires, se résolvant en quelques jours. Il s'agit notamment de douleurs au site d'injection, de fatigue, de maux de tête, de douleurs musculaires, de frissons, de douleurs articulaires et de fièvre. Durant les essais cliniques relatifs aux vaccins à ARNm, certains ÉI, dont de la fièvre, sont plus fréquents après la deuxième dose; ce n'était pas le cas pour le vaccin contre la COVID-19 d'AstraZeneca.
- De très rares cas d'un syndrome spécifique présentant des caillots sanguins graves (à des sites inhabituels tels que la thrombose du sinus veineux cérébral) avec une thrombocytopénie concomitante ont été rapportés après l'administration de vaccins à vecteur viral. Un dépistage précoce et un traitement approprié sont critiques. Des études pour mieux comprendre ce syndrome souvent appelé thrombocytopénie thrombotique immunitaire induite par le vaccin (TTIV) sont en cours. Les personnes qui ont présenté une thrombose veineuse ou artérielle avec thrombocytopénie à la suite de l'administration d'un vaccin à vecteur viral contre la COVID-19 ne devraient pas recevoir une deuxième dose d'un vaccin à vecteur viral contre la COVID-19.
- De très rares cas de myocardite et de péricardite après l'administration des vaccins à ARNm contre la COVID-19 ont été signalés, le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose. La majorité des cas signalés étaient bénins et les personnes ont tendance à récupérer rapidement. Les recherches sont en cours. Par mesure de précaution, les personnes qui ont souffert de myocardite ou de péricardite après l'administration d'une première dose d'un vaccin à ARNm contre la COVID-19 devrait reporter la deuxième dose de la série vaccinale jusqu'à ce que plus de renseignements soient disponibles. Le CCNI continuera à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.
- De très rares cas de syndrome de fuite capillaire (SFC) ont été signalés après l'administration du vaccin contre la COVID-19 d'AstraZeneca [1-3]. Certains patients affectés ont reçu un diagnostic antérieur de SFC qui constitue une affection grave et potentiellement mortelle caractérisée par des épisodes aigus d'œdème des membres, d'hypotension, d'hémoconcentration et d'hypoalbuminémie. Les personnes ayant des antécédents de SFC ne devraient pas recevoir le vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD.
- Il n'existe actuellement que peu de données probantes sur les différences d'efficacité potentielle, d'efficacité réelle ou d'innocuité du vaccin entre les personnes ayant

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préalablement été infectées par le SRAS-CoV-2 et celles qui ne l'avaient pas encore été au moment de la vaccination.

Qui

Le CCNI fait les recommandations suivantes :

Une série complète de vaccins à ARNm contre la COVID-19 devrait être proposée de préférence aux personnes appartenant au groupe d'âge autorisé qui ne présentent pas de contre-indications au vaccin.

Un vaccin à vecteur viral contre la COVID-19 peut être proposé aux personnes appartenant au groupe d'âge autorisé qui ne présentent pas de contre-indications au vaccin pour initier une série lorsque d'autres vaccins autorisés contre la COVID-19 sont contre-indiqués ou inaccessibles. Le consentement éclairé devrait inclure une discussion sur les risques et les symptômes de la TTIV, ainsi que sur la nécessité de consulter immédiatement un médecin en cas d'apparition de symptômes.

Une série complète de vaccins contre la COVID-19 actuellement autorisés peut être proposée :

- aux personnes appartenant au groupe d'âge autorisé, sans contre-indications au vaccin, qui ont déjà eu une infection par le SRAS-CoV-2 confirmée par réaction en chaîne de la polymérase (RCP). Il n'est pas nécessaire de procéder à un test de dépistage d'une infection antérieure au SRAS-CoV-2 avant la vaccination contre la COVID-19.

Le CCNI recommande également ce qui suit :

- Les programmes de vaccination systématique et la vaccination avec d'autres vaccins recommandés par le CCNI devraient se poursuivre pendant la pandémie de COVID-19 avec une mitigation des risques de transmission de COVID-19 pendant le processus de vaccination, comme indiqué dans les Lignes directrices provisoires sur la continuité des programmes d'immunisation pendant la pandémie de COVID-19.

- Les essais cliniques évaluant les vaccins contre la COVID-19 devraient continuer à être encouragés de façon à inclure les personnes potentiellement vulnérables aux maladies liées à des facteurs biologiques (p. ex., affections préexistantes, fragilité, grossesse et allaitement, immunodéficience) et sociaux (p. ex., résidence dans des établissements de soins de longue durée ou dans des lieux surpeuplés/éloignés, appartenance à une population racialisée, profession) afin de s'assurer que les options en matière de vaccins sont corroborées par de solides données sur l'innocuité, l'immunogénicité et l'efficacité potentielle, comme l'indiquent les directives du CCNI sur les priorités de recherche pour les vaccins contre la COVID-19 à l'appui des décisions de santé publique. De plus, le CNNI recommande la continuation des essais cliniques et des suivis des participants aussi longtemps que possible du point de vue éthique afin d'établir le niveau d'immunité nécessaire pour prévenir la maladie, la durée de protection, l'efficacité potentielle chez diverses sous-populations et l'innocuité à moyen et à long termes.

- En plus des activités de pharmacovigilance des vaccins qui sont en cours au Canada avec les essais cliniques de Phase 4 et les études post-commercialisation, il est recommandé de mener des recherches supplémentaires et de surveiller la vaccination contre la COVID-19, en particulier parmi les populations qui ne sont pas actuellement incluses dans les essais

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cliniques (p. ex., les personnes enceintes, les personnes allaitantes, les personnes immunodéprimées, les personnes âgées vivant dans des établissements de soins collectifs).

Le CCNI continue à recommander les éléments suivants pour guider la prise de décision éthique, comme l'indique son document Orientations préliminaires sur les principales populations à immuniser en priorité contre la COVID-19 :

- Des efforts devraient être fournis pour améliorer l'accès aux services de vaccination afin de réduire les iniquités en matière de santé, sans aggraver la stigmatisation ou la discrimination, et pour faire participer les populations systémiquement marginalisées et les populations racialisées à la planification des programmes d'immunisation.

- Les administrations devraient assurer une surveillance étroite et rapide de l'innocuité, de l'efficacité réelle des vaccins et de la couverture vaccinale dans différentes populations clés, ainsi qu'une immunisation efficace et utile des populations des communautés difficiles d'accès, éloignées et isolées.

- Des efforts devraient être fournis pour améliorer les connaissances sur les bienfaits des vaccins en général et des vaccins contre la COVID-19, lorsque chacun d'entre eux sera disponibles, afin de lutter contre la désinformation et communiquer de manière transparente sur les décisions d'attribution des vaccins contre la COVID-19.

Comment

- Les vaccins contre la COVID-19 actuellement autorisés et disponibles sont administrés par voie intramusculaire (IM) en deux doses (Pfizer-BioNTech, Moderna, AstraZeneca) ou en une dose (Janssen).
- Lorsque la première dose d'une série de vaccins contre la COVID-19 est un vaccin à ARNm, le même produit de vaccin à ARNm devrait être proposé pour la dose suivante s'il est facilement disponible. Lorsque le même produit vaccinal à base d'ARNm n'es pas facilement disponible ou est inconnu, un autre produit vaccinal à base d'ARNm contre la COVID-19 recommandé dans ce groupe d'âge peut être considéré comme étant interchangeable et devrait être proposé pour compléter la série.
- Lorsque la première dose d'une série de vaccins contre la COVID-19 est celui d'AstraZeneca/COVISHIELD, soit le vaccin d'AstraZeneca/COVISHIELD ou un vaccin à ARNm peut être proposé pour la dose suivante afin de compléter la série. Toutefois, un produit de vaccin à ARNm est privilégié comme dose ultérieure en raison des données probantes émergentes, y compris la possibilité d'une meilleure réponse immunitaire et l'innocuité des calendriers hétérologues. Les personnes ayant déjà reçu deux doses du vaccin AstraZeneca/COVISHIELD sont considérées comme étant protégées et n'ont pas besoin d'un autre vaccin.
- Il n'est pas nécessaire de procéder à des tests sérologiques avant ou après la vaccination contre la COVID-19 pour évaluer l'immunité préalable au SRAS-CoV-2 ou la réponse immunitaire au vaccin.
- Les vaccins contre la COVID-19 ne devraient pas être administrés simultanément avec d'autres vaccins vivants ou inactivés pour le moment, à moins que ces autres vaccins ne soient nécessaires pour la prophylaxie post-exposition.
- Les vaccins contre la COVID-19 ne devraient pas être administrés simultanément avec des anticorps monoclonaux ou du plasma de convalescents.

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Pourquoi

- La pandémie de COVID-19 a provoqué une morbidité et une mortalité importantes, ainsi que des perturbations sociales et économiques au Canada et dans le monde entier.
- Les vaccins contre la COVID-19 autorisés dont l'utilisation est recommandée par le CCNI dans la présente déclaration se sont révélés sûrs (malgré de très rares cas de TTIV ayant été signalés à la suite de la vaccination avec les vaccins à vecteur viral contre la COVID-19), et efficaces contre la COVID-19 symptomatique confirmée en laboratoire, et semblent protéger contre les maladies sévères, les hospitalisations et les décès attribuables à la COVID-19.

I. INTRODUCTION

L'objectif de la réponse du Canada à la pandémie est de réduire au minimum le risque de maladie grave et de décès tout en atténuant les perturbations sociales pouvant être subies par la population durant la pandémie de COVID-19. L'objectif de la réponse immunitaire contre la COVID-19 du Canada est le suivant : Permettre au plus grand nombre de Canadiens d'être vaccinés contre la COVID-19 et le plus rapidement possible, tout en veillant à ce que les populations à haut risque soient prioritaires.

Le présent document d'orientation fournira des recommandations sur l'utilisation du ou des vaccins contre la COVID-19 autorisés et disponible dont l'utilisation est approuvée au Canada, et au fur et à mesure de l'évolution des données probantes sur ces vaccins.

Il y a quatre (4) vaccins contre la COVID-19 dont l'utilisation est actuellement autorisée au Canada.

1. L'utilisation du vaccin contre la COVID-19 de Pfizer-BioNTech a été autorisée au Canada le 9 décembre 2020 pour les personnes de 16 ans et plus. Le 5 mai 2021, Santé Canada a étendu l'autorisation d'ordonnance provisoire du vaccin contre la COVID-19 de Pfizer-BioNTech aux adolescents de 12 à 15 ans.
2. L'utilisation du vaccin contre la COVID-19 de Moderna au Canada pour les personnes de 18 ans et plus a été autorisée le 23 décembre 2020.
3. L'utilisation du vaccin contre la COVID-19 d'AstraZeneca au Canada pour les 18 ans et plus a été autorisée le 26 février 2021.
    - Santé Canada a autorisé deux fabricants à produire ce vaccin mis au point par AstraZeneca et l'Université d'Oxford : AstraZeneca et le Serum Institute of India (SII). Le CCNI n'a pas examiné en particulier les données probantes concernant le vaccin du SII, mais Santé Canada a jugé que les vaccins du SII et d'AstraZeneca étaient comparables. L'autorisation du vaccin contre la COVID-19 du SII (COVISHIELD) a été fondée sur sa comparabilité avec le vaccin contre la COVID-19 d'AstraZeneca, déterminée en évaluant et en comparant directement les procédés et contrôles de fabrication, ainsi que les caractéristiques de qualité des deux produits. Les résultats de cette comparaison effectuée par Santé Canada ont permis de déterminer que les deux produits étaient suffisamment similaires et que l'efficacité potentielle, l'immunogénicité et l'innocuité du COVISHIELD pouvaient être inférées des études non cliniques et cliniques du vaccin contre la COVID-19 d'AstraZeneca
4. L'utilisation du vaccin contre la COVID-19 de Janssen au Canada pour les 18 ans et plus a été autorisée le 5 mars 2021.

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Les données probantes sur la COVID-19 et les vaccins contre la COVID-19 évoluent rapidement. À ce jour, le CCNI a publié les documents d'orientation fondés sur des données probantes suivants :

1. Priorités de recherche pour les vaccins contre la COVID-19 à l'appui des décisions de santé publique (archivées), afin d'orienter les essais cliniques des vaccins expérimentaux contre la COVID-19 pour protéger contre l'infection, les maladies graves et les décès causés par le SRAS-CoV-2.
2. Orientations préliminaires sur les principales populations à immuniser en priorité contre la COVID-19, pour planifier l'attribution efficace, efficiente et équitable d'un vaccin contre la COVID-19, à terme, lorsque l'approvisionnement initialement limité en vaccins nécessitera d'immuniser certaines populations avant les autres.
3. Orientations sur l'administration prioritaire des premières doses du vaccin contre la COVID-19 pour une administration prioritaire efficace et équitable des premières doses de vaccin contre la COVID-19 afin d'aider à la planification de l'attribution des premiers programmes d'immunisation contre la COVID-19.
4. Orientations sur l'établissement de l'ordre de priorité des principales populations à immuniser contre la COVID-19 pour une répartition équitable, éthique et efficace des vaccins contre la COVID-19 autorisés, dans le contexte de l'arrivée échelonnée de l'approvisionnement en vaccins, qui nécessitera de vacciner en priorité certaines populations avant les autres.
5. Réponse rapide du CCNI : Allongement des intervalles entre les doses des vaccins contre la COVID-19 pour optimiser les campagnes de vaccination précoces et la protection des populations au Canada (archivée) pour maximiser le nombre de personnes bénéficiant de la première dose de vaccin en prolongeant l'intervalle pour la deuxième dose jusqu'à quatre mois après la première. Cette réponse rapide a été suivie d'une déclaration plus complète du CCNI (archivée) donnant un aperçu détaillé des données probantes et des considérations qui ont conduit à la recommandation du CCNI.
6. Réponse rapide du CCNI : Recommandation sur l'utilisation du vaccin d'AstraZeneca contre la COVID-19 chez les jeunes adultes (archivée) directives élaborées en réponse à l'enquête du thrombocytopénie immunitaire prothrombotique induite par le vaccin (TIPIV) [ci-après désignée par le terme de thrombocytopénie thrombotique induite par le vaccin (TTIV)] suivant son administration contre la COVID-19 d'AstraZeneca fait l'objet d'un examen plus approfondi.
7. La recommandation sur l'utilisation du vaccin contre la COVID-19 de Pfizer-BioNTech chez les adolescents de 12 à 18 ans (recommandant qu'une série complète du vaccin contre la COVID-19 de Pfizer-BioNTech soit proposée aux personnes de 12 à 18 ans sans contre-indications au vaccin).
8. Réponse rapide du CCNI : Interchangeabilité des vaccins contre la COVID-19 autorisés (archivée) pour fournir des conseils sur l'interchangeabilité des vaccins contre la COVID-19 autorisés dans le contexte d'un calendrier de primovaccination à deux doses pour la vaccination contre la COVID-19 au Canada.
9. Les recommandations sur l'utilisation du vaccin contre la COVID-19 (archivées) ont été publiées à l'origine le 12 décembre 2020 et mises à jour de façon itérative avec l'arrivée de nouvelles données probantes et avec l'autorisation de vaccins contre la COVID-19 supplémentaires. Cette déclaration reflète les orientations les plus récentes.

Objectif des orientations:

L'objectif de la présente déclaration du comité consultatif est de fournir des conseils éclairés sur l'utilisation efficace et équitable des vaccins contre la COVID-19 autorisés et disponibles au Canada. Ce document évolutif sera mis à jour au fur et à mesure que l'utilisation des vaccins contre la COVID-

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19 sera autorisée et disponible au Canada et que les données probantes sur ces vaccins évolueront ou que la situation pandémique justifie des changements d'orientation. Dans le présent document d'orientation, les données probantes et la justification des recommandations ainsi que les lacunes actuelles dans les connaissances seront résumées. Les résumés des données probantes sur les caractéristiques de vaccins contre la COVID-19 particuliers figureront dans les annexes.

II. MÉTHODOLOGIE

Les détails du processus d'élaboration des recommandations du CCNI peuvent être consultés ailleurs [4,5].

En bref, voici les étapes générales de la préparation d'une déclaration du comité consultatif du CCNI :

1. Synthèse des connaissances;
2. Synthèse du corpus de données probantes sur les avantages et les risques, compte tenu de la qualité des données probantes synthétisées et de l'ampleur et de la certitude des effets observés dans l'ensemble des études;
3. Transposition des données probantes en recommandations.

Afin d'élaborer des recommandations détaillées et appropriées au sujet des programmes d'immunisation, le CCNI tient compte d'un certain nombre de facteurs. Outre l'évaluation critique des données probantes sur le fardeau de la maladie et les caractéristiques des vaccins (comme l'innocuité, l'immunogénicité, l'efficacité potentielle et réelle), le CCNI utilise un cadre publié revu par des pairs et des outils fondés sur des données probantes pour s'assurer que les questions liées à l'éthique, à l'équité, à la faisabilité et à l'acceptabilité (ÉÉFA) sont systématiquement évaluées et intégrées dans ses orientations [5]. Le secrétariat du CCNI a appliqué ce cadre avec les outils fondés sur des données probantes qui l'accompagnent (filtres d'éthique intégrés, matrice d'équité, matrice de faisabilité, matrice d'acceptabilité) afin de prendre systématiquement en compte ces facteurs programmatiques dans l'élaboration de recommandations claires, complètes et appropriées pour une prise de décision transparente en temps utile. Pour plus de détails sur l'élaboration et l'application du cadre ÉÉFA et des outils fondés sur des données probantes (y compris les filtres et matrices déjà mentionnés), voir le document https://doi.org/10.1016/j.vaccine.2020.05.051 (en anglais seulement).

Pour les besoins de la présente déclaration du comité consultatif, le CCNI a utilisé le cadre GRADE (Grading of Recommendations, Assessment, Development and Evaluation) pour élaborer des recommandations axées sur la population. De plus amples renseignements sur ce cadre peuvent être consultés dans le document : https://training.cochrane.org/resource/grade-handbook (en anglais seulement).

Le 25 novembre 2020, le CCNI a examiné et approuvé les questions de politiques importantes utilisées pour orienter l'élaboration des recommandations et a évalué les résultats en fonction de leur importance pour la prise de décision. Compte tenu de l'évolution des données probantes, le CCNI a de nouveau évalué les résultats le 21 mars 2021. Le Comité canadien sur l'immunisation (CCI) a fourni des commentaires sur ces questions afin d'assurer leur harmonisation avec les besoins du programme. D'importantes considérations d'ordre éthique concernant les questions de politiques clés ont été présentées le 26 novembre 2020, le 15 décembre 2020, le 26 janvier 2021 et le 6 avril 2021 au Groupe consultatif en matière d'éthique en santé publique de l'ASPC, qui a fourni

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une évaluation des considérations éthiques pertinentes pour l'élaboration de recommandations. La synthèse des connaissances et l'évaluation de la qualité des données probantes non publiées des essais cliniques ont été effectuées par le secrétariat du CCNI et ont été corroborées par l'évaluation des résultats par le CCNI. Les données probantes non publiées des essais cliniques de Phases 1, 2 et 3 ont été présentées au Groupe de travail sur les vaccins contre les maladies infectieuses à haut risque et au CCNI pour discussion. Les recommandations proposées ont ensuite été présentées et approuvées à l'occasion de réunions d'urgence du CCNI. On trouvera dans le texte une description des considérations pertinentes, des justifications des décisions et des lacunes dans les connaissances.

Dates clés

- Le vaccin contre la COVID-19 de Pfizer-BioNTech a fait l'objet d'une discussion le 4 décembre 2020, et les recommandations connexes ont été approuvées le 7 décembre 2020.
- Le vaccin contre la COVID-19 de Moderna a fait l'objet d'une discussion le 14 décembre 2020, et les recommandations connexes ont été approuvées le 17 décembre 2020.
- Le vaccin contre la COVID-19 d'AstraZeneca a fait l'objet d'une discussion le 19 janvier, le 28 janvier et le 24 février 2021, et les recommandations connexes ont été approuvées le 24 février 2021.
- Les considérations relatives à un intervalle prolongé entre les doses des vaccins autorisés dans le contexte d'un approvisionnement limité en vaccins, et les précisions des recommandations pour les populations qui avaient été exclues des essais cliniques ou représentées par un moindre nombre de participants, ont été discutées le 7 janvier 2021 et approuvées le 8 janvier 2021.
- Des données probantes supplémentaires sur un intervalle prolongé de 4 mois entre les doses de vaccin autorisées dans le contexte d'un approvisionnement en vaccins limité ont été examinées les 8, 19 et 24-25 février 2021. Les recommandations connexes ont été approuvées le 1er mars 2021. Entre le 25 et le 28 mars 2021, les membres du CCNI ont réexaminé ces recommandations dans la mesure où elles concernent des groupes de population spécifiques.
- Des données probantes supplémentaires provenant d'études d'observation de l'efficacité réelle du vaccin d'AstraZeneca chez les personnes âgées de plus de 65 ans ont été examinées le 10 mars 2021. Les recommandations connexes ont été approuvées le 13 mars 2021.
- L'évolution des données probantes sur la TTIV suivant l'administration du vaccin contre la COVID-19 d'AstraZeneca a été révisée pour la première fois le 24 mars 2021 et les recommandations connexes ont été approuvées le 28 mars 2021. Les nouvelles données probantes y compris le rapport d'évaluation de l'innocuité de Santé Canada publié le 14 avril 2021, ont fait l'objet d'une révision officielle les 13, 15, 17 et 20 avril 2021. Les recommandations mises à jour ont été approuvées le 20 avril 2021.
- Le vaccin contre la COVID-19 de Janssen a fait l'objet d'une discussion les 16 et 25 mars et les 13 et 26 avril 2021, et les recommandations ont été approuvées le 30 avril 2021.
- L'évolution des données probantes sur les intervalles prolongés a été revue les 11 et 13 mai 2021. Le 13 mai 2021, le CCNI a mis à jour la recommandation connexe dans le contexte d'un approvisionnement accru en vaccins contre la COVID-19.
- Des données probantes supplémentaires au sein des populations exclues des essais cliniques ou inclues en petit nombre ont été revues les 4 et 13 mai 2021. Les recommandations connexes sur la vaccination contre la COVID-19 chez les personnes qui

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sont immunodéprimées, qui souffrent d'une maladie auto-immune, qui sont enceintes ou qui allaitent, ont été revues et approuvées le 13 mai 2021.

- Le 9 mai 2021, le CCNI a revu les données probantes disponibles sur l'utilisation du vaccin contre la COVID-19 de Pfizer-BioNTech chez les adolescents de 12 à 15 ans et a approuvé les recommandations connexes le 11 mai 2021.
- Des données probantes sur les calendriers de vaccination mixtes contre la COVID-19 ont été présentées et examinées par le CCNI le 26 mai 2021 et les recommandations connexes ont été approuvées le 30 mai 2021. Les données probantes émergentes ont été examinées le 9 juin et la recommandation connexe sur l'interchangeabilité dans une série de vaccins lorsque la première dose est un vaccin d'AstraZeneca/COVISHIELD a été révisée et approuvée le 11 juin 2021.
- Le CCNI a examiné sa recommandation sur l'administration simultanée de vaccins contre la COVID-19 avec d'autres vaccins et l'a mise à jour le 9 juin 2021.
- Les données probantes sur la myocardite et la péricardite ont été présentées et examinées par le CCNI les 18 mai, 1 juin, 15 juin, 21 juin et 24 juin 2021. Le CCNI a approuvé l'inclusion de renseignements mis à jour dans les directives du CCNI le 27 juin 2021.

III. ÉPIDÉMIOLOGIE

Les renseignements sur la COVID-19 évoluent continuellement. La section suivante décrit la base des connaissances actuelles, et souligne les meilleures données canadiennes disponibles, lorsque possible. Pour accéder aux mises à jour les plus récentes concernant certains aspects précis, voir les liens ci-dessous.

Description de la maladie

Agent infectieux

La COVID-19 est causée par le SRAS-CoV-2, qui a été reconnu pour la première fois à Wuhan, en Chine, en décembre 2019.

Transmission

Les données probantes actuelles laissent entendre que le SRAS-CoV-2 se propage par les gouttelettes respiratoires et les aérosols créés lorsqu'une personne infectée tousse, éternue, chante, crie ou parle. Une personne peut être infectieuse pendant une période pouvant aller jusqu'à trois jours avant de présenter des symptômes.

Vous trouverez de plus amples renseignements liés à la transmission du SRAS-CoV-2 sur les pages Web de l'ASPC COVID-19 : Principaux modes de transmission et Signes, symptômes et gravité de la COVID-19 : Guide à l'intention des cliniciens.

Variants préoccupants

Des mutations génétiques du virus SRAS-CoV-2 dont certaines rendent le virus plus infectieux et plus transmissible ont été repérées. Elles pourraient également avoir une incidence sur la gravité de la maladie et sur le niveau de protection offert par les vaccins.

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De plus amples informations sur les VP signalés au Canada sont disponibles dans la mise à jour de l'épidémiologie de la COVID-19. La mise à jour épidémiologique hebdomadaire de la COVID-19 de l'Organisation mondiale de la Santé (OMS) fournit un résumé de la distribution mondiale et des données probantes émergentes concernant les VP et les VI. Les différences entre les VP et les VI se trouvent dans Variants du SRAS-CoV2 : définitions, classifications et actions de santé publique nationales.

Le CCNI continuera à surveiller l'épidémiologie et les données probantes concernant les VP et les vaccins contre la COVID-19.

Facteurs de risque

Tout le monde peut être infecté par le SRAS-CoV-2. Cependant, certaines populations sont plus exposées au virus (p. ex., en raison de leur cadre de vie ou de travail), et d'autres sont exposées à un risque accru de maladie et de complications sévères (p. ex., hospitalisation et décès) en raison de divers facteurs biologiques (p. ex., âge avancé, affection préexistante) et sociaux (p. ex., statut socio-économique, appartenance à une population racialisée) qui peuvent se croiser. L'exposition et le risque de facteurs de maladie sévère peuvent se chevaucher, ce qui augmente encore le risque. Toute combinaison de ces facteurs, ainsi que l'accès variable aux services de soins de santé, peut avoir des conséquences disproportionnées pour certaines populations particulières caractérisées par des taux accrus d'infection et de maladie, de maladie sévère, d'hospitalisation ou de décès.

Voir la Déclaration du comité consultatif du CCNI sur les principales populations à vacciner en priorité contre la COVID-19 et la matrice d'équité [6] pour obtenir un résumé des iniquités associées à la COVID-19, les raisons possibles de ces iniquités et leurs recoupements, et les interventions suggérées pour réduire les iniquités et améliorer l'accès aux vaccins. Les orientations sur l'établissement de l'ordre de priorité des principales populations à immuniser contre la COVID-19 du CCNI s'appuient sur le cadre fondamental pour l'allocation équitable, éthique et efficace des vaccins autorisés contre le COVID-19 dans le contexte de l'arrivée échelonnée de l'approvisionnement en vaccins qui nécessitera d'offrir des vaccins à certaines populations plus tôt que d'autres. Ces conseils ont été éclairés par l'évolution des données probantes sur les facteurs de risque de la COVID-19.

Le Tableau 1 résume les populations à risque souffrant de complications sévères liées à la COVID-19 (hospitalisations et/ou décès) sur la base des résultats issus d'une revue rapide mise à jour des données probantes [7] provenant d'études menées dans des pays membres de l'Organisation de coopération et de développement économiques (OCDE), ainsi que les populations à risque accru d'exposition à la COVID-19 (en raison de l'absence de distanciation physique et/ou de l'accès réduit aux mesures de prévention et de contrôle des infections) qui sont identifiées, en partie, dans les rapports canadiens (épidémiologiques et analytiques).

La revue du Alberta Research Centre for Health Evidence (ARCHE) a trouvé de solides données probantes (de certitude modérée à élevée) sur l'augmentation double du taux de mortalité attribuable à la COVID-19 chez les personnes de 60-69 ans par rapport aux personnes de moins de 60 ans [7]. Une revue antérieure menée par ARCHE a trouvé des données probantes de certitude modérée sur l'augmentation de cinq fois le taux de mortalité et d'hospitalisation chez les personnes de plus de 70 ans (par rapport aux personnes de 45 ans et moins) [8]. Les études qui ont été réalisées en fonction de l'âge sur un continuum ou selon de petits incréments ont systématiquement trouvé que les risques d'hospitalisation et de mortalité augmentaient avec l'âge (c.-à-d. une augmentation relative du risque d'environ 2-6 % et 5-10 % par année)[7].

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La revue de ARCHE a trouvé de solides données probantes (certitude modérée à élevée) sur l'augmentation d'au moins deux fois le taux de mortalité attribuable à la COVID-19 chez les personnes souffrant d'un petit nombre d'affections médicales (classifiées de Niveau 1 au Tableau 1) [7]. La revue a trouvé des données probantes de faible certitude sur l'augmentation d'au moins deux fois le taux de mortalité attribuable à la COVID-19, et/ou des données probantes de certitude faible à modérée sur l'augmentation d'au moins deux fois le taux d'hospitalisation pour une liste plus longue d'affections médicales (classifiées de Niveau 2). On a constaté que les personnes souffrant de deux affections médicales ou plus présentaient une augmentation d'au moins deux fois plus d'hospitalisations et de mortalité attribuables à la COVID-19 (certitude de preuve modérée). De même, dans les populations de 21 ans et moins, on a constaté que les personnes souffrant de deux affections médicales ou plus présentaient au moins deux fois plus d'hospitalisations pour la COVID-19 (certitude de preuve modérée). Toutefois, il n'y a aucune donnée probante directe sur quelle combinaison d'affections médicales augmente ce risque [7].

Il faut faire preuve de prudence en matière d'interprétation des données probantes de faible certitude (c.-à-d. pour les affections médicales de Niveau 2). À mesure que les données probantes s'accumulent, les associations observées pourraient changer. Par exemple, une revue rapide antérieure menée par ARCHE [9] a trouvé des données probantes de faible certitude sur l'augmentation d'au moins deux fois le taux d'hospitalisation ou de décès chez les hommes, les personnes atteintes d'une maladie du foie et chez les personnes souffrant d'insuffisance cardiaque. Au fur et à mesure que les données probantes s'accumulent, il existe actuellement des données probantes plus solides concernant l'association faible ou nulle de complications sévères à ces populations. La liste des affections médicales figurant au Tableau 1 peut ne pas être exhaustive, car elle n'est fondée que sur les données probantes issues des études publiées qui sont incluses dans la revue ARCHE.

Tableau 1. Résumé des facteurs de risque liés aux complications sévères attribuables à la COVID-19 et du risque accru d'exposition à la COVID-19

Risque accru des complications sévères attribuables à la COVID-19 (hospitalisations/décès) [a]	**Risque accru de l'exposition à la COVID-19** [7] **(p. ex., en raison de l'incapacité de respecter la distanciation physique, de l'accès réduit à la CPI)** [b]
Augmentation de l'âge (données probantes solides) (sur la base de données probantes de certitude modérée d'au moins 2 fois l'augmentation des décès) • ≥60 ans (particulièrement ≥ 70 ans) [7]	• Résidents et personnel des lieux d'habitation collective qui assurent des soins aux personnes âgées • Travailleurs de la santé de première ligne • Adultes dans les communautés autochtones • Résidents et personnel d'autres lieux d'habitation collective (p. ex., habitations pour les travailleurs migrants, abris, établissements correctionnels, foyers de groupe)
Affections médicales – Niveau 1 (données probantes solides) [7] (sur la base de données probantes de certitude modérée à élevée d'au moins deux fois l'augmentation des décès) • Syndrome de Down • Maladie rénale au stade terminal • Épilepsie • Maladie des motoneurones, sclérose en plaques, myasthénie grave, maladie de Huntington [d]	

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Risque accru des complications sévères attribuables à la COVID-19 (hospitalisations/décès) [a]	Risque accru de l'exposition à la COVID-19 [7] (p. ex., en raison de l'incapacité de respecter la distanciation physique, de l'accès réduit à la CPI) [b]
• Diabète de type 1 et de type 2 **Affections médicales – Niveau 2 (données probantes limitées)** [7] **Niveau 2a** *(sur la base de données probantes de faible certitude concernant une augmentation d'au moins deux fois le taux de mortalité* • Paralysie cérébrale • Trouble psychiatrique grave (schizophrénie, trouble schizo-affectif ou trouble bipolaire); en combinaison avec la prise de médicaments pour l'affection en question depuis 6 mois • Obésité classe III (IMC de 40 kg/m^2 ou plus) • Maladie de Parkinson • Anémie falciforme ou immunodéficience sévère, greffe (tous genres) • Greffe d'organe solide • Greffe de moelle osseuse ou greffe de cellules souches récente • Cancer métastatique • Chimiothérapie ou radiothérapie récente ou en cours **Niveau 2b** *(sur la base de données probantes de certitude faible ou modérée concernant l'augmentation d'au moins 2 fois le taux d'hospitalisation)* • Accident cérébrovasculaire antécédent • Grossesse (tout stage) • Fragilité (chez les personnes à domicile de communautés et hors communautés; des échelles de barème dont la perte de poids, l'épuisement, l'activité physique, la vitesse de marche, la force de préhension, la santé générale, l'invalidité, la présence d'une maladie, la démence, les chutes, le mieux-être mental) • Vascularite • Obésité – toutes les classes (IMC de plus de 30 kg/m^2	• Adultes dans les communautés racialisées et marginalisées • Premiers intervenants (p.ex., policiers, pompiers) • Travailleurs essentiels de première ligne qui ne peuvent pas travailler virtuellement
Risque accru des complications sévères (hospitalisations/décès)[c] et risque accru d'exposition [7]	
• Résidents d'établissements de soins de longue durée • Minorités visibles (comprend essentiellement Asiatique du sud, Chinois, Noir, Philippin, Latino-Américain, Arabe, Asiatique du Sud-Est, Asiatique de l'Ouest, Coréen, Japonais)	

[a] Tiré d'une revue rapide de données probantes de pays membres de l'OCDE concernant une association indépendante aux complications sévères attribuables à la COVID-19.

[b] Tiré, en partie, des rapports épidémiologiques canadiens.

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[c] Identifié par l'entremise d'une revue rapide d'études canadiennes pouvant avoir une association avec des hospitalisations et des décès attribuables à la COVID-19. Ces études peuvent ne pas avoir tenu compte d'autres co-variables.

[d] Ces affections ont été regroupées dans une seule étude; les données probantes concernant les affections individuelles sont soit non disponibles ou de faible certitude.

La liste des affections médicales au Tableau 1 peut être différente de celle d'autres administrations en raison des différences au niveau de l'épidémiologie locale et des niveaux distincts de données probantes prises en compte.

Les données probantes sur les facteurs de risque liés à la COVID-19 continuent d'évoluer.

Spectre de la maladie clinique

La durée médiane de la période d'incubation des non-variants du SRAS-CoV-2 a été estimée à 5 ou 6 jours entre l'exposition et l'apparition des symptômes, la plupart des individus (97,5 %) constatant le développement de symptômes dans les 11,5 jours suivant l'exposition. La période d'incubation varie de 1 à 14 jours.

Le tableau clinique et les symptômes de la COVID-19 varient en fréquence et en gravité. À ce jour, il n'existe aucune liste de symptômes pour laquelle une spécificité élevée ou une sensibilité élevée à la COVID-19 n'a été validée.

Pour de plus amples renseignements sur le spectre de la maladie clinique, voir la page Web de l'ASPC : Signes, symptômes et gravité de la COVID-19 : Guide à l'intention des cliniciens.

Incidence de la maladie

À l'échelle mondiale

Des données internationales actualisées sur les cas et les décès liés à la COVID-19 sont accessibles à l'adresse suivante :
https://sante-infobase.canada.ca/covid-19/international/

Des mises à jour épidémiologiques hebdomadaires mettant en évidence les principales données mondiales, régionales et nationales sur les cas et les décès liés à la COVID-19 sont accessibles auprès de l'OMS à l'adresse suivante (en anglais seulement) :
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

À l'échelle nationale

Des données actualisées à l'échelle nationale, provinciale et territoriale sur les cas et les décès liés à la COVID-19 au Canada au fil du temps peuvent être consultées sur la page Web de l'ASPC suivante : Maladie à coronavirus (COVID-19) : Mise à jour sur l'éclosion.

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IV. VACCINS

La section suivante résume les renseignements sur les vaccins contre la COVID-19 dont l'utilisation est autorisée au Canada. De plus amples renseignements sur les vaccins figurent aux Annexes A à D. Un panorama de la situation actuelle concernant tous les vaccins expérimentaux contre la COVID-19 au stade de l'évaluation clinique peut être consulté sur la page Web de l'OMS suivante (en anglais seulement) : Draft landscape of COVID-19 candidate vaccines. Aux termes de l'Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19, Santé Canada peut prendre des décisions réglementaires à l'égard des vaccins contre la COVID-19 pour lesquels les essais cliniques de Phase 3 en vue de l'autorisation de l'utilisation au Canada sont achevés.

La plupart des vaccins expérimentaux en cours d'élaboration dont l'utilisation pourrait être autorisée au Canada font appel à diverses technologies pour administrer la protéine de spicule (protéine S) du SRAS-CoV-2 aux personnes vaccinées. Cette protéine est exprimée à la surface du SRAS-CoV-2 et constitue une cible majeure pour la liaison et la neutralisation des anticorps ainsi que pour les réponses immunitaires à médiation cellulaire.

Vaccins à ARNm

Les vaccins contre la COVID-19 à ARN messager (ARNm) contiennent des nucléotides modifiés délivrant des instructions génétiques pour neutraliser les protéines des spicules du SRAS-CoV-2. Une formulation de nanoparticules lipidiques permet d'acheminer l'ARNm dans les cellules du sujet vacciné. Une fois à l'intérieur du cytoplasme d'une cellule, l'ARNm ordonne aux mécanismes de production de protéines intracellulaires de libérer l'antigène qui s'ancrera sur les protéines externes des spicules transmembranaires. L'ARNm ne pénètre pas dans le noyau de la cellule et ne modifie pas l'ADN humain. Pour induire des réactions immunitaires humorales et cellulaires, le système immunitaire est mobilisé à la fois par les protéines des spicules transmembranaires et par les récepteurs immunitaires porteurs des antigènes qui se fixeront aux spicules. L'ARNm, les nanoparticules lipidiques, et les protéines de spicule sont dégradés ou excrétés dans les jours ou les semaines qui suivent l'immunisation. Les vaccins à ARNm ne sont pas des vaccins vivants et ne peuvent pas provoquer d'infection chez l'hôte.

Le Canada s'est procuré et prévoit un nombre suffisant de vaccins à ARNm pour vacciner en totalité, avant l'automne 2021, l'ensemble de la population canadienne admissible à l'heure actuelle.

Vaccins à vecteur viral non réplicatif

Les vaccins contre la COVID-19 basés sur des plateformes de vecteurs viraux se servent d'un virus modifié pour transporter les gènes contenant le code des protéines de spicule du SRAS-CoV-2 dans les cellules hôtes. Un virus vecteur est un type d'adénovirus qui a été modifié pour porter les gènes de la COVID-19 et pour en empêcher la réplication. Ces modifications visent à empêcher le vecteur viral de propager la maladie (c'est-à-dire qu'ils ne se reproduisent pas). Une fois à l'intérieur de la cellule, les gènes de la protéine de spicule du SRAS-CoV-2 sont transcrits en ARNm dans le noyau et se traduisent en protéines dans le cytosol de la cellule. Le vaccin d'AstraZeneca contient un vecteur adénovirus modifié du chimpanzé (ChAd). Le vaccin de Janssen utilise un vecteur adénovirus humain modifié de sérotype 26 (Ad26).

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IV.1 Préparations des vaccins contre la COVID-19 dont l'utilisation est approuvée et disponible au Canada

Tableau 2. Vaccins contre la COVID-19 dont l'utilisation est disponible au Canada

Nom de marque du produit	Vaccin contre la COVID-19 de Pfizer-BioNTech	Vaccin contre la COVID-19 de Moderna	Vaccin contre la COVID-19 d'AstraZeneca / COVISHIELD	Vaccin contre la COVID-19 de Janssen
Type de vaccin	ARNm	ARNm	Vecteur viral non réplicatif (ChAd)	Vecteur viral non réplicatif (Ad26)
Date d'autorisation au Canada	9 décembre 2020 (16 ans et plus); 5 mai 2021 (12 ans et plus)	23 décembre 2020	26 février 2021	5 mars 2021
Groupe d'âge pour lequel le vaccin est approuvé	12 ans et plus	18 ans et plus	18 ans et plus	18 ans et plus
Dose	0,3 mL (30 mcg d'ARNm)[a]	0,5 mL (100 mcg d'ARNm)	0,5 mL (5×10^{10} particules virales)	0,5 mL (5×10^{10} particules virales)
Calendrier autorisé[b]	2 doses, à 3 semaines d'intervalle	2 doses, à 4 semaines d'intervalle	2 doses, de 4 à 12 semaines d'intervalle	1 dose
Voie d'administration	IM	IM	IM	IM
Nature de l'antigène	Protéine de spicule en perfusion transmembranaire	Protéine de spicule en perfusion transmembranaire	Protéine de spicule transmembranaire	Protéine de spicule en perfusion transmembranaire
Adjuvant (si présent)	Aucun	Aucun	Aucun	Aucun
Exigences relatives à l'entreposage primaire avant la perforation[c]	-80 °C à -60 °C	-25 °C à -15 °C[d]	De +2 °C à +8 °C	De +2 °C à +8 °C
Options d'entreposage supplémentaires avant perforation[c]	Flacons congelés : -25 °C à -15 °C pendant 2 semaines au maximum[e] Décongelés sous frigération : 1 mois à +2 °C à +8 °C Décongelés à température ambiante 2 heures à une température maximale de +25 °C	30 jours à une température comprise entre +2 °C et +8 °C OU 24 heures à une température comprise entre +8 °C et +25 °C	De +2 °C à +8 °C	De +2 °C à +8 °C
Diluant	Oui	Non	Non	Non
Limite d'utilisation après perforation	6 heures à une température comprise entre +2 °C et +25 °C[f]	24 heures entre +2 °C et +25 °C	6 heures à température ambiante (jusqu'à +30 °C) **Ou** 48 heures de +2 °C à +8 °C.	3 heures à température ambiante (jusqu'à +25 °C) **Ou** 6 heures de +2 °C à +8 °C.
Présentations offertes	Flacon multidose (6 doses)[a], sans agent de conservation	Flacon multidose (10 doses), sans agent de conservation	Fiole multidoses (8 et 10 doses), sans agent de conservation	Fiole multidose (5 doses), sans agent de conservation

Abréviations : ChAd : adénovirus du chimpanzé; Ad26 : adénovirus humain modifié 26; IM : intramusculaire; ARNm : acide ribonucléique messager

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[a] Après dilution, la fiole contient 6 doses de 0,3 mL. Cependant, des seringues et/ou des aiguilles à faible volume mort peuvent être utilisées pour prélever 6 doses dans chaque fiole. L'information incluse dans la présente monographie au sujet du nombre de doses par fiole après la dilution a préséance sur la mention du nombre de doses sur les étiquettes et les boîtes de fioles. En utilisant des seringues et des aiguilles standards, le volume pourrait être insuffisant pour permettre le prélèvement d'une 6e dose dans une même fiole. Voir la monographie du produit disponible dans la Base de données sur les produits pharmaceutiques de Santé Canada pour le choix du diluant, les instructions de dilution, et le type de seringues qui peuvent être utilisées pour extraire 6 doses d'un seul fiole.
[b] Calendrier autorisé selon la monographie de produit. Pour de plus amples informations relatives aux recommandations du CCNI sur les intervalles entre les doses, voir le Tableau 3.
[c] À l'abri de la lumière pendant l'entreposage.
[d] Ne pas le stocker sur de la glace sèche ou à une température inférieure à -40 °C.
[e] Les flacons entreposés entre -25 °C et -15 °C pendant un maximum de 2 (deux) semaines peuvent être remis une fois dans les conditions d'entreposage recommandées de -80 °C à -60 °C. La durée totale cumulée d'entreposage des flacons entre -25 °C et -15 °C devrait faire l'objet d'un suivi et ne devrait pas dépasser 2 (deux) semaines.
[f] Une fois dilué, le vaccin doit être utilisé dans les six (6) heures.

IV.2 Efficacité potentielle et efficacité réelle

Comme seules des données provenant d'essais cliniques à court terme sont disponibles, la durée de protection offerte par le vaccin contre la COVID-19 est actuellement inconnue. Cependant, des études sont en cours.

La section suivante présente les principales données sur l'efficacité potentielle et l'efficacité réelle des vaccins à ARNm contre la COVID-19 qui ont été autorisés (vaccin contre la COVID-19 de Pfizer-BioNTech, vaccin contre la COVID-19 de Moderna) et des vaccins à vecteur viral contre la COVID-19 autorisés (vaccin contre la COVID-19 d'AstraZeneca, vaccin contre la COVID-19 de Janssen) uniquement. Pour de plus amples renseignements concernant le plan d'étude, y compris la population étudiée, la durée du suivi et l'efficacité potentielle en ce qui a trait aux vaccins autorisés et disponibles, voir le résumé des données probantes à l'Annexe A (vaccin contre la COVID-19 de Pfizer-BioNTech), à l'Annexe B (vaccin contre la COVID-19 de Moderna), à l'Annexe C (vaccin contre la COVID-19 d'AstraZeneca), et à l'Annexe D (vaccin contre la COVID-19 de Janssen).

Efficacité potentielle contre la COVID-19 symptomatique

Les vaccins à ARNm contre la COVID-19 actuellement autorisés se sont révélés très efficaces à court terme contre la maladie symptomatique confirmée (présence d'un ou plusieurs symptômes, et confirmation en laboratoire de l'infection par le SRAS-CoV-2). Le calendrier autorisé des vaccins à ARNm à deux doses est tout aussi efficace chez les adultes présentant une ou plusieurs comorbidités, ainsi que chez les adolescents (vaccin contre la COVID-19 de Pfizer-BioNTech) les jeunes adultes et les personnes âgées.

Lors des essais cliniques, le vaccin à vecteur viral contre la COVID-19 d'AstraZeneca a montré une efficacité potentielle modérée à court terme contre la COVID-19 symptomatique (présence d'au moins un symptôme prédéfini de la COVID-19 plus confirmation en laboratoire de l'infection par le SRAS-CoV-2) chez les adultes de 18 à 64 ans au moins deux semaines après avoir reçu la série complète des deux doses standard du vaccin. Les données des essais cliniques montrent que l'efficacité potentielle a augmenté avec l'intervalle entre les doses. À l'heure actuelle, les données des essais cliniques chez les adultes de 65 ans et plus sont insuffisantes pour évaluer l'efficacité du vaccin dans cette tranche d'âge. Le vaccin est tout aussi efficace chez les adultes de 18 ans et plus avec et sans comorbidités prédéfinies (présence d'une ou plusieurs maladies cardiovasculaires légères à modérées et contrôlées, de maladies respiratoires, de diabète ou d'obésité). En l'absence initiale de données suffisantes issues d'essais cliniques à ce jour sur l'efficacité potentielle du vaccin contre la COVID-19 d'AstraZeneca chez les personnes âgées de 65 ans et plus, une revue de trois études d'observation réalisées au R.-U. et publiées sous forme de prétirés sur l'efficacité réelle du

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vaccin dans ce groupe d'âge a été réalisée afin d'éclairer les recommandations du CCNI dans ce groupe d'âge. Les conclusions de cet examen sont résumées à l'Annexe C. Ces études fournissent des estimations d'efficacité réelle après la première dose du vaccin d'AstraZeneca et ont montré une réduction du risque de maladie symptomatique et d'hospitalisation qui semble atteindre un niveau comparable à celui observé chez les personnes d'âge similaire ayant reçu une dose de vaccin à ARNm.

Le vaccin contre la COVID-19 de Janssen démontre une efficacité potentielle modérée contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant entre 14 et 28 jours après la vaccination, sachant que la définition de la maladie modérée inclut la présence d'un ou deux signes et symptômes ou plus parmi un éventail relativement large qui sont compatibles avec la COVID-19, plus la confirmation en laboratoire de l'infection par le SRAS-CoV-2. Les estimations ponctuelles de l'efficacité potentielle du vaccin à ces deux points dans le temps pour divers groupes d'âge sont similaires à l'estimation globale, y compris chez les participants à l'étude âgés de 65 ans et plus qui ont représenté environ 20 % de la population étudiée. Les estimations ponctuelles de l'efficacité potentielle du vaccin à 14 jours après la vaccination sont comparables chez les participants à l'étude avec et sans une ou plusieurs comorbidités. En revanche, l'estimation ponctuelle de l'efficacité potentielle chez les participants présentant des comorbidités est un peu plus faible, à 28 jours après la vaccination. L'efficacité potentielle du vaccin de Janssen a été fondée sur des essais cliniques qui ont été menées dans des pays où des VP circulaient largement (Afrique du Sud et Brésil), ce qui peut avoir influé sur son efficacité globale. Ceci contraste avec les essais cliniques d'autres vaccins contre la COVID-19 autorisés.

Les données des essais cliniques établissent que les vaccins à ARNm contre la COVID-19 autorisés sont utiles à court terme chez les individus présentant ou non des signes d'infection antérieure par le SRAS-CoV-2. Toutefois, les participants dont l'infection par le SRAS-CoV-2 a été confirmée en laboratoire (à l'aide d'un test d'amplification des acides nucléiques, comme la technique RT-PCR) avant l'inscription ont été exclus des essais, et le nombre de participants à l'essai présentant des signes d'infection antérieure (selon la définition de ce terme énoncée dans le protocole de l'essai) et chez lesquels la COVID-19 symptomatique a été confirmée au cours de l'essai était peu nombreux. Par conséquent, l'efficacité potentielle dans cette population et la façon dont elle se compare à l'efficacité chez les participants sans signe d'infection antérieure sont inconnues pour le moment. L'efficacité potentielle du vaccin contre la COVID-19 de Janssen chez les personnes antérieurement infectées et confirmées n'est pas concluante actuellement en raison de la petite taille de l'échantillon, et cette complication n'a pas été évaluée dans le cas du vaccin contre la COVID-19 d'AstraZeneca.

La première dose de vaccins contre la COVID-19 autorisés s'est révélé offrir à tout le moins une protection à court terme contre la COVID-19 confirmée. Pour les vaccins à ARNm, l'efficacité potentielle la plus élevée s'observe après l'administration de la deuxième dose. Il n'existe actuellement aucune donnée probante concernant l'utilité à moyen ou à long terme du vaccin contre la COVID-19 autorisé, mais des essais sont en cours, et la présente déclaration sera mise à jour à mesure que les données probantes deviendront disponibles.

Efficacité potentielle et efficacité réelle contre la forme sévère de la maladie

Les essais cliniques sur les vaccins contre la COVID-19 autorisés et disponibles ont évalué l'efficacité potentielle contre la forme sévère de la maladie, mais ils n'ont pas tous fourni des données suffisantes pour évaluer l'efficacité potentielle contre les hospitalisations ou les décès.

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Les vaccins à ARNm et le vaccin contre la COVID-19 de Janssen autorisés semblent être efficaces contre les complications sévères liées à la COVID-19 selon des données provenant d'essais cliniques à des fins d'autorisation (les issues sévères ont été définies comme la COVID-19 confirmée en laboratoire présentant l'une des caractéristiques supplémentaires suivantes : signes cliniques au repos indicateurs d'une maladie systémique sévère; insuffisance respiratoire; signes de choc; dysfonctionnement rénal, hépatique ou neurologique aigu important; admission à l'unité de soins intensifs [USI] ou décès). Toutefois, le nombre de cas sévères observés à ce jour était faible dans l'essai clinique de Pfizer-BioNTech chez les participants de 16 ans et plus et trop faible dans les essais cliniques d'AstraZeneca pour évaluer l'efficacité potentielle. Aucun cas sévère n'a été identifié chez les adolescents de 12 à 15 ans dans l'essai clinique de Pfizer-BioNTech. L'efficacité potentielle contre l'hospitalisation n'a pas été évaluée dans les essais cliniques menés sur les vaccins à ARNm mais les essais cliniques portant sur les vaccins à vecteur viral suggèrent un effet protecteur contre l'hospitalisation. À ce jour, très peu de décès associés à la COVID-19 ont été recensés dans le cadre des essais cliniques, ce qui rend difficile l'évaluation de l'efficacité potentielle pour ce résultat. Toutefois, parmi les décès attribuables à la COVID-19 recensés dans les essais cliniques, aucun ne s'est produit chez les participants à l'étude ayant reçu des vaccins contre la COVID-19.

Les données probantes émergentes en conditions réelles et provenant d'études menées au R.-U. [10-12], en Israël [13-15][16], aux États-Unis (É.-U.) [17] et au Canada [18][19] suggèrent une efficacité réelle modérée à élevée contre les formes sévères de COVID-19 après l'administration d'une première ou deuxième dose de vaccin à ARNm contre la COVID-19 chez les adultes [10-15, 17, 18][16] et après l'administration d'une première dose du vaccin contre la COVID-19 d'AstraZeneca [10-12], y compris chez les populations âgées [10-12, 15] et fragiles [10]. L'hospitalisation liée à la COVID-19 était la complication sévère la plus souvent évaluée [10-13, 17][16], tandis que peu d'études ont fourni des estimations de l'efficacité réelle contre les formes sévères de la maladie [13, 14] et le décès [11, 13, 18]. Des données probantes émergentes provenant d'études israéliennes suggèrent une efficacité réelle élevée du vaccin contre la COVID-19 de Pfizer-BioNTech contre les formes sévères de la maladie [13, 14], les hospitalisations liées à la COVID-19 [13][16] et les décès [16] après l'administration d'une deuxième dose du vaccin. Des études sur les vaccins contre la COVID-19 sont en cours et les nouvelles données sur leur efficacité réelle contre les complications sévères liées à la COVID-19 seront évaluées au fur et à mesure.

Efficacité potentielle et efficacité réelle contre l'infection asymptomatique et la transmission
Les données préliminaires issues de l'essai clinique en cours sur le vaccin contre la COVID-19 de Moderna ont démontré une plus faible prévalence de positivité du SRAS-CoV-2 par RCP chez les participants asymptomatiques à un moment donné (après la première dose mais avant la deuxième dose) et par conséquent, de l'excrétion virale, dans le groupe qui a reçu le vaccin par rapport au groupe placebo. Toutefois, les données actuelles sont insuffisantes pour tirer des conclusions. Les analyses exploratoires du vaccin à vecteur viral d'AstraZeneca n'ont pas montré d'efficacité potentielle contre les infections asymptomatiques par le SRAS-CoV-2 confirmées, mais le nombre d'infections asymptomatiques était faible. L'essai clinique du vaccin contre la COVID-19 de Janssen a montré que ce vaccin offre une protection modérée contre l'infection par la COVID-19 asymptomatique et non détectée. Des études sont en cours pour ces vaccins.

Des données probantes ont commencé à émerger des études post-commercialisation menées en Israël [13], au R.-U. [20] et aux É.-U. [21] sur l'efficacité réelle des vaccins contre la COVID-19 face à l'infection asymptomatique chez les adultes. Les estimations de l'efficacité réelle contre la COVID-19 de Pfizer-BioNTech face à l'infection par le SRAS-CoV-2 sans symptômes signalés étaient de modérées à élevées après la première dose [13, 20] (en fonction du temps écoulé depuis la

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vaccination) et élevées après la deuxième dose [13, 20]. Des résultats similaires ont été signalés pour les vaccins à ARNm contre la COVID-19 en général (ex. Moderna and Pfizer-BioNTech) [21]. Dans une étude britannique, les infections asymptomatiques par le SRAS-CoV-2 étaient nettement moins susceptibles de survenir chez les participants vaccinés [20]. Il n'y a pas encore de résultats particuliers aux autres vaccins contre la COVID-19, mais des études sont en cours.

Efficacité potentielle et efficacité réelle contre les variants

Les données probantes sur la protection et l'efficacité réelle diverses qui sont offertes par les vaccins à ARNm contre la COVID-19 autorisés (vaccin contre la COVID-19 de Pfizer-BioNTech, vaccin contre la COVID-19 de Moderna) et par les vaccins contre la COVID-19 à vecteur viral (vaccin contre la COVID-19 d'AstraZeneca, vaccin contre la COVID-19 de Janssen) contre les variants du SRAS-CoV-2 sont en pleine évolution. Voir le Tableau 5 pour consulter le résumé de ces données probantes.

L'essai clinique du vaccin de Janssen a été mené pendant l'émergence des VP du SRAS-CoV-2. Dans le cadre des tests effectués au cours de l'essai, une partie des isolats de cas a été séquencée génétiquement, et parmi les isolats séquencés, un peu plus des deux tiers des isolats du Brésil appartenaient au VI P.2 (zêta) et presque tous les isolats d'Afrique du Sud correspondaient au VP B.1.351 (béta). Les estimations ponctuelles de l'efficacité potentielle du vaccin contre une infection par le SRAS-CoV-2 confirmée symptomatique modérée à sévère/critique 28 jours suivant l'administration du vaccin sont comparables à l'estimation globale de l'efficacité potentielle contre cette complication au Brésil et en Afrique du Sud.

Il existe des données probantes montrant que les vaccins de Pfizer-BioNTech et d'AstraZeneca protègent contre le VP B.1.1.7 (alpha). Bien que la protection contre l'infection par le VP B.1.617.2 (delta) après la première dose des vaccins de Pfizer-BioNTech et d'AstraZeneca semble être réduite par rapport à d'autres souches, les données émergentes suggèrent que le vaccin de Pfizer-BioNTech offre une très bonne protection et le vaccin d'AstraZeneca offre une bonne protection contre l'infection par le VP B.1.617.2 (delta) après la deuxième dose. De plus, les vaccins offrent une bonne protection contre l'hospitalisation après les premières doses. Il existe également des données émergentes sur l'efficacité potentielle et l'efficacité réelle des vaccins à ARNm contre le VP B.1.351 (béta). Des données probantes provenant des essais cliniques du vaccin de Janssen indiquent qu'il protège contre l'infection à la COVID-19 symptomatique modérée à sévère/critique dans des régions où le VP B.1.351 (béta) et le VI P.2 (zêta) circulent largement. L'essai clinique d'AstraZeneca a été mené lorsque la souche B.1.351 (béta) était la plus courante en Afrique du Sud, et l'efficacité potentielle du vaccin n'était pas démontré contre cette souche.

Le CNNI continuera à surveiller les données probantes et à mettre à jour ses recommandations si nécessaire.

IV.3 Immunogénicité

Aucun corrélat immunologique de protection n'a été déterminé pour le SRAS-CoV-2; par conséquent, toutes les données probantes immunologiques à l'appui de l'efficacité du vaccin sont indirectes et ne peuvent être utilisées directement pour estimer l'efficacité potentielle et l'efficacité réelle.

Il existe plusieurs lacunes importantes dans les connaissances qui nuisent à la compréhension des réponses immunitaires au vaccin contre la COVID-19 :

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- les types de réponses immunitaires qui sont importants pour la protection contre l'infection, la maladie sévère ou la transmission;
- le niveau de réponses immunitaires humorales et cellulaires qui est nécessaire pour conférer une protection;
- la durabilité des réponses immunitaires et leur évolution dans le temps;
- la comparaison entre les réponses immunitaires à une infection naturelle et les réponses provoquées par un vaccin;
- la différence dans les réponses immunitaires selon la population (p. ex., chez les individus immunodéprimés, les enfants) ou selon l'état sérologique pour le SRAS-CoV-2 (c.-à-d. une COVID-19 antérieure);
- la différence dans les réponses immunitaires en fonction de l'infection antérieure par des coronavirus autres que le SRAS-CoV-2.

En raison des limitations du nombre de participants évalués pour les conséquences liées à l'immunogénicité et des données sur la durée du suivi dans les essais cliniques sur la COVID-19, les données probantes à long terme sur l'immunogénicité sont inconnues. Cependant, des études sont en cours.

La section suivante présente les principales données sur l'immunogénicité des vaccins à ARNm contre la COVID-19 qui ont été autorisés (vaccin contre la COVID-19 de Pfizer-BioNTech, vaccin contre la COVID-19 de Moderna) et des vaccins contre la COVID-19 à vecteur viral (vaccin contre la COVID-19 d'AstraZeneca, vaccin contre la COVID-19 de Janssen) uniquement. Pour de plus amples renseignements concernant le plan d'étude, y compris la population étudiée, la durée du suivi et l'immunogénicité en lien avec les vaccins autorisés, voir le résumé des données probantes à l'Annexe A (vaccin contre la COVID-19 de Pfizer-BioNTech), à l'Annexe B (vaccin contre la COVID-19 de Moderna), à l'Annexe C (vaccin contre la COVID-19 d'AstraZeneca) et à l'Annexe D (vaccin contre la COVID-19 de Janssen).

Réponses immunitaires humorales

Tous les vaccins contre la COVID-19 autorisés induisent des réactions immunitaires humorales, y compris des réactions à anticorps de liaison et de neutralisation. Les réactions humorales ont atteint un pic après la deuxième dose de vaccin à ARNm et après la deuxième dose de vaccin d'AstraZeneca chez les participants qui n'avaient pas été infectés auparavant. Les réponses immunitaires humorales furent élevées après l'administration de la seule dose du vaccin de Janssen. Certains vaccins entraînent des réactions immunitaires plus fortes chez les populations jeunes.

Les vaccins à base de vecteurs viraux peuvent induire des réactions immunitaires anti-vectorielles, qui peuvent avoir un impact sur l'efficacité potentielle et réelle futures du vaccin et peuvent varier selon l'âge, la dose et l'intervalle entre les doses.

Réponses immunitaires cellulaires

Il a été démontré que tous les vaccins contre la COVID-19 autorisés et disponibles déclenchent des réactions immunitaires cellulaires. Les réactions immunitaires cellulaires ont augmenté après la deuxième dose du vaccin à ARNm contre la COVID-19, tandis que les réponses au vaccin contre la COVID-19 d'AstraZeneca se sont maintenues ou ont diminué après la deuxième dose. Les réponses immunitaires cellulaires étaient présentes après l'administration d'une seule dose du vaccin de Janssen.

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IV.4 Administration des vaccins

Pour de plus amples renseignements spécifiques aux vaccins, voir le dépliant du produit ou l'information contenue dans la monographie de produit disponible dans la Base de données sur les produits pharmaceutiques de Santé Canada. Voir le chapitre Méthodes d'administration des vaccins dans le Guide canadien d'immunisation (GCI), Partie 1 - Information clé sur l'immunisation, pour de plus amples renseignements.

Comme pour l'administration normale de tous les vaccins, les vaccins contre la COVID-19 devraient être administrés dans des conditions permettant de gérer l'anaphylaxie. Voir le site Anaphylaxie et autres réactions aiguës après la vaccination dans le Guide canadien d'immunisation (GCI), Partie 2 – La sécurité des vaccins pour de plus amples renseignements sur la gestion de l'anaphylaxie après la vaccination

IV.4.1 Dose, voie d'administration et calendrier

Dose

Vaccin contre la COVID-19 de Pfizer-BioNTech

Chaque dose est d'un volume de 0,3 mL après dilution, et contient 30 mcg d'ARNm de la protéine de spicule du SRAS-CoV-2.

La dose du vaccin contre la COVID-19 de Pfizer-BioNTech (0,3 mL) est unique par rapport à celle de la plupart des vaccins systématiques. Il convient de prendre des précautions particulières pour s'assurer que la dose correcte est prélevée dans le flacon multidose.

Vaccin contre la COVID-19 de Moderna

Chaque dose fait un volume de 0,5 mL et contient 100 mcg d'ARNm de la protéine de spicule du SRAS-CoV-2.

Aucune dilution n'est requise

Vaccin contre la COVID-19 d'AstraZeneca

Chaque dose fait un volume de 0,5 mL et contient 5×10^{10} particules de la protéine de spicule du SRAS-CoV-2.

Aucune dilution n'est requise.

Vaccin contre la COVID-19 de Janssen

Chaque dose fait un volume de 0,5 mL et contient 5×10^{10} particules de la protéine de spicule du SRAS-CoV-2.

Aucune dilution n'est requise.

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Voie d'administration

Les vaccins contre la COVID-19 sont administrés par injection IM dans le muscle deltoïde. Le muscle deltoïde du bras est le site d'injection privilégié chez les adolescents et les adultes (à moins que la masse musculaire ne soit pas adéquate ou que la vaccination à ce site ne soit pas possible. Dans ces cas, on peut utiliser la partie antérolatérale de la cuisse).

Pour en savoir plus, voir le chapitre Méthodes d'administration des vaccins dans le GCI, Partie 1 – Information clé sur l'immunisation.

Calendrier

Voir le Tableau 3 pour le résumé des calendriers d'immunisation pour les vaccins contre la COVID-19 autorisés et disponible.

Tableau 3. Calendrier d'immunisation, par vaccin contre la COVID-19

Produit de vaccination	Calendrier d'immunisation	Intervalle minimal	Intervalle autorisé	Intervalle prolongé[a]
Vaccin contre la COVID-19 de Pfizer-BioNTech	Calendrier à 2 doses	19 jours[b]	21 jours	16 semaines
Vaccin contre la COVID-19 de Moderna	Calendrier à 2 doses	21 jours[c]	28 jours	16 semaines
Vaccin contre la COVID-19 d'AstraZeneca	Calendrier à 2 doses	28 jours	De 4 à 12 semaines[d]	16 semaines[d]
Vaccin contre la COVID-19 de Janssen	Calendrier à 1 dose	S.O.	S.O.	S.O.

[a] En se fondant sur les données probantes émergentes concernant la protection offerte par la première dose d'une série de deux doses du vaccin contre la COVID-19 actuellement autorisée et disponible au Canada, le CCNI recommande que, dans le contexte d'un approvisionnement limité en vaccins contre la COVID-19 et d'une pandémie en cours, les juridictions maximisent le nombre de personnes bénéficiant de la première dose du vaccin en prolongeant la deuxième dose du vaccin contre la COVID-19 jusqu'à quatre mois après la première. Le CCNI continuera à surveiller les données probantes et à mettre à jour cet intervalle si nécessaire.
[b] La base de cet intervalle minimum est que la conception per-protocole de l'essai clinique du vaccin contre la COVID-19 de Pfizer-BioNTech était de 19-23 jours.
[c] La base de cet intervalle minimum est que la majorité des participants à l'essai clinique du vaccin contre la COVID-19 de Moderna ont reçu la seconde dose 21 à 42 jours après la première, conformément à la fenêtre prédéfinie.
[d] L'essai clinique du vaccin contre la COVID-19 d'AstraZeneca a démontré une efficacité potentielle optimale lorsque l'intervalle entre la première et la deuxième dose était ≥12 semaines.

Pour les calendriers de vaccination mixtes contre la COVID-19, l'intervalle minimal entre les doses devrait être fondé sur l'intervalle minimal du produit utilisé pour la première dose (p.ex., le vaccin contre la COVID-19 de Pfizer-BioNTech devrait être offert au moins 28 jours après le vaccin contre la COVID-19 d'AstraZeneca). Les recommandations sur les intervalles prolongés s'appliquent aux calendriers de vaccination mixtes.

PROTÉGÉ B

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Voir le chapitre Calendrier d'administration des vaccins du GCI, Partie 1 – Information clé sur l'immunisation pour de plus amples renseignements.

Intervalles prolongés pour les vaccins contre la COVID-19 afin d'optimiser le déploiement précoce du vaccin et la protection de la population

Actuellement, aucune donnée n'est disponible sur l'efficacité potentielle à moyen ou long terme des vaccins contre la COVID-19. En général, il n'est pas nécessaire de recommencer une série de vaccins interrompue (intervalle observé plus important que celui recommandé), puisque la prolongation des intervalles entre les doses ne diminuent pas la concentration finale d'anticorps pour la plupart des produits à doses multiples (primovaccination-rappel). Pour de nombreux autres vaccins à doses multiples administrés à l'âge adulte à l'aide d'autres technologies de production de vaccins, la première dose confère la plus grande partie de la protection à court terme, les doses supplémentaires étant principalement destinées à prolonger la protection à plus long terme. Toutefois, le suivi dans les essais cliniques sur les vaccins contre la COVID-19 a été de courte durée, on ignore la durée de la protection après une seule dose ou les deux, et les vaccins à ARNm et de vecteurs viraux représentent des technologies de production de vaccins relativement nouvelles.

La morbidité et la mortalité liées à la COVID-19 sont en cours. La prolongation de l'intervalle jusqu'à la deuxième dose d'un vaccin contre la COVID-19 permet de maximiser l'approvisionnement en vaccins afin d'immuniser le plus grand nombre de personnes le plus rapidement possible. Les principes de l'immunologie indiquent qu'un intervalle prolongé entre les doses d'amorçage et de rappel d'une série de vaccins entraîne une réponse meilleure et plus durable. Voir la déclaration du CCNI sur l'allongement des intervalles entre les doses des vaccins contre la COVID-19 pour optimiser les campagnes de vaccination précoces et la protection des populations au Canada dans le contexte d'un approvisionnement limité en vaccins (archivée), pour un résumé des données probantes.

Il sera important de faire le suivi de l'efficacité réelle du vaccin chez les individus pour lesquels la deuxième dose est retardée ou non administrée pour diverses raisons (p. ex., non-respect du rendez-vous d'immunisation de suivi) afin d'éclairer les recommandations futures et de garantir la prise de la deuxième dose le plus rapidement possible. Le CCNI continuera à surveiller les données probantes et à mettre à jour ses recommandations si nécessaire.

IV.4.2 Doses de rappel et revaccination

Il n'existe actuellement aucune donnée probante sur la nécessité de doses de rappel du vaccin contre la COVID-19 une fois la série de vaccins terminée. Vu l'émergence des VP qui pourraient diminuer l'efficacité réelle du vaccin, des doses de vaccin supplémentaires pourraient se révéler nécessaires. Le CCNI continuera à surveiller les données probantes et à mettre à jour ses recommandations si nécessaire.

IV.4.3 Interchangeabilité

Interchangeabilité des vaccins autorisés contre la COVID-19 dans une série de vaccins lorsque la première dose est comme suit :

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Vaccin à ARNm contre la COVID-19

Le CCNI recommande que, s'il est facilement disponible*, le même produit vaccinal à ARNm contre la COVID-19 soit proposé pour la dose suivante d'une série de vaccins commencée avec un vaccin à ARNm contre la COVID-19. Toutefois, lorsque le même vaccin à ARNm contre la COVID-19 n'est pas facilement disponible*, ou est inconnu, un autre vaccin à ARNm contre la COVID-19 recommandé pour une utilisation dans ce groupe d'âge peut être considéré comme étant interchangeable et devrait être proposé pour compléter la série vaccinale. La dose précédente devrait être comptée et la série n'a pas besoin d'être recommencée.

(Forte recommandation du CCNI)

*facilement disponible = facile d'accès au moment de la vaccination sans délai ni gaspillage de vaccin

Vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD

Le CCNI recommande que, même si un vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD ou un produit vaccinal à ARNm contre la COVID-19 peut être proposé pour la dose suivante d'une série de vaccins commencée avec un vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD, un produit d'ARNm contre la COVID-19 est privilégié comme dose ultérieure, en raison de données probantes émergentes, y compris la possibilité d'une meilleure réponse immunitaire et l'innocuité des calendriers hétérologues. Quel que soit le produit proposé, une série complète de deux doses est importante pour la protection; la dose précédente devrait être comptée et la série n'a pas besoin d'être recommencée. Les personnes qui reçoivent deux doses du vaccin d'AstraZeneca/COVISHIELD sont considérées comme étant protégées et n'ont pas besoin d'un autre vaccin.

(Recommandation discrétionnaire du CCNI)

Aucune donnée n'existe actuellement sur l'interchangeabilité des vaccins à ARNm contre la COVID-19. Toutefois, il n'y a aucune raison de croire que l'achèvement d'une série de vaccins à ARNm avec un autre produit à ARNm autorisé entraînera des problèmes d'innocuité supplémentaires ou une déficience de protection.

Des données probantes émergentes indiquent que les calendriers mixtes de vaccins à vecteur viral et à ARNm contre la COVID-19 avec des intervalles de dosage entre 4 et 12 semaines ont des profils d'innocuité acceptables qui peuvent être associés à une réactogénicité systémique accrue à court terme, qui est potentiellement augmentée avec des intervalles plus courts entre les vaccins. Les données probantes actuelles indiquent également que les réponses immunitaires humorales et cellulaires (y compris les réponses contre les VP) après la première dose du vaccin d'AstraZeneca augmentent après l'administration du vaccin de Pfizer-BioNTech comme deuxième dose avec un intervalle de 8 à 12 semaines [22], et sont équivalentes ou supérieures aux réponses immunitaires suivant un calendrier homologue à deux doses du vaccin d'AstraZeneca ou de Pfizer.

En raison du risque de TTIV associé à la deuxième dose du vaccin d'AstraZeneca/COVISHIELD, proposer un autre produit ayant un profil d'innocuité plus acceptable et un profil d'immunogénicité comparable attendu, tout en permettant aux personnes de faire un choix éclairé est éthiquement

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justifiable. Cela devrait entraîner une accessibilité et une acceptabilité accrues pour les personnes à qui on a initialement proposé une première dose du vaccin d'AstraZeneca/COVISHIELD, y compris celles qui sont les plus à risque de contracter la COVID-19. Compte tenu du risque de la TTIV associé au vaccin de Janssen, il ne devrait pas être proposé aux personnes ayant reçu une première dose du vaccin d'AstraZeneca/COVISHIELD et préférant recevoir un autre produit pour leur deuxième dose. Pour de plus amples détails sur la TTIV, voir Thrombose avec thrombocytopénie suivant l'administration de vaccins à vecteur viral contre la COVID-19.

Pour les calendriers de vaccination mixtes contre la COVID-19, l'intervalle minimal entre les doses devrait être fondé sur l'intervalle minimal du produit utilisé pour la première dose (p.ex., le vaccin contre la COVID-19 de Pfizer-BioNTech devrait être offert au moins 28 jours après le vaccin contre la COVID-19 d'AstraZeneca). Les recommandations sur les intervalles prolongés s'appliquent aux calendriers de vaccination mixtes. Voir le Tableau 3 pour de plus amples renseignements sur les intervalles recommandés pour les vaccins contre la COVID-19 autorisés.

Les recommandations concernant l'interchangeabilité des vaccins contre la COVID-19 sont conformes aux orientations actuelles du CCNI sur l'interchangeabilité des vaccins utilisés pour la même indication et contenant des antigènes comparables. Conformément aux principes de base de vaccinologie [23], on s'attend à ce que la combinaison de différents vaccins contre la COVID-19 qui induisent une réponse immunitaire contre la protéine de spicule du SRAS-CoV-2 conduira à une réponse immunitaire robuste. Tous les vaccins contre la COVID-19 actuellement autorisés au Canada utilisent la protéine de spicule du virus SRA-CoV-2 comme antigène. La protéine de spicule produite par les vaccins à ARNm (Pfizer-BioNTech, Moderna) et de Janssen est stabilisée dans la conformation de préfusion tandis que le vaccin d'AstraZeneca produit une protéine de spicule de type sauvage dans diverses conformations, y compris la préfusion.

De très rares cas de myocardite (inflammation du muscle cardiaque) et de péricardite (inflammation de la muqueuse autour du cœur) suivant l'administration de vaccins à ARNm contre la COVID-19 ont été signalés au Canada et à l'échelle internationale, le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose d'une série homologue de deux doses comparativement à la première dose. La majorité des cas sont bénins et les personnes récupèrent rapidement. Pour de plus amples renseignements sur la myocardite/péricardite, voir Myocardite ou péricardite suivant l'administration d'un vaccin à ARNm contre la COVID-19.

La surveillance active de l'efficacité réelle et l'innocuité d'un calendrier mixte sont importantes, et un enregistrement précis des vaccins reçus sera essentiel. Le CCNI continuera à surveiller les données probantes et à mettre à jour ses recommandations si nécessaire. Pour de plus amples renseignements sur les données probantes relatives aux calendriers de vaccination mixtes contre la COVID-19, voir la Réponse rapide du CCNI : Interchangeabilité des vaccins autorisés contre la COVID-19 (archivée).

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IV.4.4 Conseils après la vaccination

Le CCNI recommande de ne pas systématiquement utiliser d'analgésiques ou d'antipyrétiques prophylactiques oraux (p. ex., l'acétaminophène ou l'ibuprofène) avant ou au moment de la vaccination, mais leur utilisation ne constitue pas une contre-indication à la vaccination. Ces médicaments peuvent être envisagés pour la gestion des ÉI (p. ex., la douleur ou la fièvre, respectivement), s'ils surviennent après la vaccination.

Des analgésiques et des antipyrétiques ont été utilisés dans les essais cliniques sur les vaccins contre la COVID-19 pour la gestion de la douleur ou de la fièvre après la vaccination. Il n'existe actuellement aucune donnée probante sur le bienfait de l'administration d'analgésiques oraux pour la prévention de la douleur causée par l'injection du vaccin ou des réactions systémiques.

Tous les patients devraient recevoir l'instruction de se faire soigner s'ils présentent des signes ou des symptômes de réaction allergique après la fin de leur période d'observation et s'ils ont quitté la clinique ou le centre de vaccination.

Toute personne vaccinée qui présente des symptômes compatibles avec la COVID-19 devrait subir un test de dépistage du virus du SRAS-CoV-2 pour documenter la survenue de l'infection, particulièrement face à l'émergence des VP. Le séquençage génétique devrait être fortement pris en compte pour les personnes infectées par le SRAS-CoV-2 après la vaccination avec une ou deux doses d'un vaccin contre la COVID-19.

Toute personne recevant un vaccin à vecteur viral contre la COVID-19 devrait être informée du récent signalement de l'ÉI reconnu lié au STT, et être avisée de consulter immédiatement un médecin si elle développe des symptômes dans les 42 jours suivant la vaccination)[24]. Il faut être particulièrement attentif aux symptômes suivants : essoufflement, douleur à la poitrine, œdème des jambes, douleur abdominale persistante, symptômes neurologiques incluant l'apparition soudaine de maux de tête ou de vision trouble aggravants sévères ou persistants, ecchymose à l'épiderme (ailleurs qu'au site de l'injection) ou pétéchies. De plus, les professionnels de la santé devraient être au courant de la TTIV, notamment le diagnostic et le traitement (voir les orientations nationales de Thrombose Canada).

Voir le chapitre Méthodes d'administration des vaccins dans le GCI, Partie 1 – Information clé sur l'immunisation pour de plus amples renseignements sur la période avant et après la vaccination.

IV.5 Dépistage sérologique

Aucun test sérologique n'est nécessaire avant ou après l'immunisation par un vaccin contre la COVID-19.

IV.6 Conditions d'entreposage

Vaccin contre la COVID-19 de Pfizer-BioNTech

Flacons congelés avant utilisation
Le vaccin contre la COVID-19 de Pfizer-BioNTech doit être conservé à de très basses températures de -80 °C à -60 °C et à l'abri de la lumière, dans l'emballage d'origine, jusqu'au moment de l'utilisation.

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Voir les directives de reglaçage (accessible à CVDVaccine.ca) pour les instructions concernant l'utilisation du contenant thermique d'origine du fabricant pour l'entreposage temporaire.

Les flacons peuvent également être entreposés entre -25 °C et -15 °C pendant deux semaines au maximum. Les flacons doivent être conservés congelés et à l'abri de la lumière, dans les cartons d'origine, jusqu'au moment de leur utilisation. Les flacons entreposés entre -25 °C et -15 °C pendant un maximum de 2 (deux) semaines peuvent être remis une fois dans les conditions d'entreposage recommandées de -80 °C à -60 °C. La durée totale cumulée d'entreposage des flacons entre -25 °C et -15 °C devrait faire l'objet d'un suivi et ne devrait pas dépasser 2 (deux) semaines.

Flacons décongelés, non percés (avant dilution)
Le vaccin contre la COVID-19 de Pfizer-BioNTech peut être décongelé et conservé entre +2 °C et +8 °C pendant (1) un mois au maximum ou à température ambiante (jusqu'à +25 °C) pendant 2 heures au maximum. Pendant l'entreposage, réduisez au minimum l'exposition à la lumière ambiante et évitez l'exposition à la lumière directe du soleil et aux rayons ultraviolets. Les flacons décongelés peuvent être manipulés à la lumière ambiante.

Ne recongelez pas les flacons décongelés.

Flacons décongelés, percés (après dilution)
Le vaccin contre la COVID-19 de Pfizer-BioNTech doit être entreposé entre +2 °C et +25 °C et utilisé dans les 6 heures suivant la dilution. Pendant l'entreposage, réduisez au minimum l'exposition à la lumière ambiante et évitez l'exposition à la lumière directe du soleil et aux rayons ultraviolets. Après la dilution, les flacons de vaccin peuvent être manipulés à la lumière ambiante.

Vaccin contre la COVID-19 de Moderna

Flacons congelés avant utilisation
Le vaccin contre la COVID-19 de Moderna devrait être conservé à des températures de -25 °C à -15 °C et à l'abri de la lumière dans son emballage d'origine. Ne pas le stocker sur de la glace sèche ou à une température inférieure à -40 °C.

Flacons décongelés, non percés
S'il n'est pas percé, le vaccin contre la COVID-19 de Moderna peut être décongelé et conservé à une température comprise entre +2 °C et +8 °C pendant 30 jours au maximum, ou à une température comprise entre +8 °C et +25 °C pendant 24 heures au maximum.

Ne recongelez pas les flacons décongelés.

Flacons décongelés, percés
Le vaccin contre la COVID-19 de Moderna peut être entreposé entre +2 °C et +25 °C mais doit être éliminé après 24 heures suivant la première perforation.

Vaccin contre la COVID-19 d'AstraZeneca

Flacon multidose non ouvert
Le vaccin d'AstraZeneca peut être conservé entre +2 °C et +8 °C et protégé de la lumière dans son emballage d'origine. Ne pas congeler.

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Flacon multidose ouvert
Après la première ouverture, la stabilité chimique et physique en cours d'utilisation a été démontrée à partir du moment où le flacon est perforé jusqu'au moment de l'administration, pendant un maximum de 6 heures à température ambiante (jusqu'à +30 °C) ou pendant 48 heures dans un réfrigérateur (+2 °C à +8 °C).

Le flacon peut être réfrigéré à nouveau, mais la durée de conservation cumulée à température ambiante ne doit pas dépasser 6 heures, et la durée de conservation cumulée totale ne doit pas dépasser 48 heures. Après ce délai, le flacon doit être jeté.

Vaccin contre la COVID-19 de Janssen

Flacon multidose non ouvert
Le vaccin de Janssen peut être conservé entre 2 °C et 8 °C et il est protégé de la lumière dans son emballage d'origine. Ne pas congeler.

Flacon multidose percé
Après le prélèvement de la première dose, le flacon/seringue rempli(e) peut être conservé(e) à 2 °C jusqu'à 8 °C pendant 6 heures au plus ou à température ambiante (25 °C au maximum) pendant 3 heures au plus, après la première perforation du flacon. Jeter si le vaccin n'est pas utilisé dans ce délai.

Pour de plus amples renseignements, voir le dépliant du produit ou l'information contenue dans la monographie de produit disponible dans la Base de données sur les produits pharmaceutiques de Santé Canada. Voir le chapitre Manipulation et entreposage des agents immunisants du GCI, Partie 1 – Information clé sur l'immunisation pour de plus amples renseignements généraux.

IV.7 Administration simultanée d'autres vaccins

Le CCNI recommande que les vaccins contre la COVID-19 ne soient pas systématiquement administrés simultanément avec d'autres vaccins (vivants ou inactivés). *(Forte recommandation du CCNI)*

À l'heure actuelle, il n'existe aucune donnée sur l'administration simultanée du vaccin contre la COVID-19 et d'autres vaccins, bien qu'un certain nombre d'études soient en cours. En l'absence de telles données, une approche préventive est recommandée en ce moment. Le potentiel d'interférence immunitaire n'est pas connu. De plus, l'administration du vaccin contre la COVID-19 seul aide à évaluer tout effet secondaire suivant l'immunisation (ESSI). Toutefois, si un vaccin contre la COVID-19 est administré par inadvertance en même temps qu'un autre vaccin, aucune des deux doses ne devrait être répétée.

En l'absence de données probantes, il serait prudent d'attendre au moins 28 jours après l'administration de toute dose d'un vaccin contre la COVID-19 avant d'administrer un autre vaccin non-COVID-19 en raison du déclenchement d'une réponse des cytokines pro-inflammatoires. Il serait prudent d'attendre au moins 14 jours après l'injection d'un autre vaccin avant d'administrer un vaccin contre la COVID-19 afin d'éviter l'attribution erronée d'un ESSI à un vaccin en particulier.

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La période d'attente minimale entre les vaccins est préventive et il peut y avoir des circonstances dans lesquelles l'administration simultanée ou un intervalle plus court peuvent être justifiés sur une base individuelle. Ces circonstances peuvent inclure les cas suivants :

- si un autre vaccin est requis pour la prophylaxie post-exposition;
- si les personnes ont besoin de calendriers de vaccination accélérés avant un traitement immunosuppresseur ou une transplantation;
- s'il existe un risque que la personne ne puisse pas terminer une série de vaccination en raison d'un accès limité aux services de date ultérieure;
- s'il permettra à une personne enceinte de recevoir le vaccin dcaT à 32 semaines de grossesse ou plus tôt;
- à l'appréciation clinique du professionnel de la santé.

Si une évaluation des risques estime que les avantages l'emportent sur les risques potentiels pour la personne, et si un consentement éclairé est fourni, une période d'attente plus courte ou l'administration simultanée de vaccins contre la COVID-19 avec d'autres vaccins (vivants ou inactivés) peut être envisagée.

Si plusieurs types de vaccins sont administrés lors d'une même visite, ils devraient être administrés à différents sites d'injection à l'aide de matériel d'injection distinct.

Le CCNI continuera à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.
Voir le chapitre Calendrier d'administration des vaccins du GCI, Partie 1 – Information clé sur l'immunisation pour de plus amples renseignements sur l'administration simultanée d'autres vaccins.

IV.8. Innocuité des vaccins et effets secondaires suivant l'immunisation

En raison des limites dans le nombre de participants et de la durée du suivi dans les essais cliniques sur la COVID-19, les données probantes à moyen et long termes sur l'innocuité des vaccins sont limitées. Toutefois, la pharmacovigilance des vaccins autorisés est en cours et les signalements en matière d'innocuité dans le monde entier sont repérés et communiqués globalement. Les essais cliniques des vaccins contre la COVID-19 autorisés excluaient les personnes ayant des antécédents de réactions indésirables sévères associés à un vaccin ou de réaction allergique sévère (p. ex., anaphylaxie) à l'un ou l'autre des composants du vaccin. Toutefois, des études sont en cours.

La section suivante présente les principales données sur l'innocuité et sur les ESSI des vaccins contre la COVID-19 autorisés. Pour plus de détails concernant la conception des essais, y compris la population étudiée et la durée du suivi, et l'innocuité des vaccins dont l'utilisation est autorisée et disponible au Canada, voir les résumés des données probantes figurant à l'Annexe A (pour le vaccin contre la COVID-19 de Pfizer-BioNTech), à l'Annexe B (pour le vaccin contre la COVID-19 de Moderna) à l'Annexe C (pour le vaccin contre la COVID-19 d'AstraZeneca) et à l'Annexe D (pour le vaccin contre la COVID-19 de Janssen). Voir l'Annexe E pour un résumé de la fréquence des ESSI pour les différents produits de vaccination contre la COVID-19.

Voir la Partie 2 – Innocuité des vaccins du GCI pour consulter les définitions des ESSI et des renseignements supplémentaires d'ordre général.

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IV.8.1 Évènements indésirables courants et très courants

Les ÉI courants sont définis comme étant ceux qui se produisent chez 1 % à moins de 10 % des personnes vaccinées; les ÉI très courants se produisent chez 10 % ou plus des personnes vaccinées. Veuillez consulter l'Annexe E pour un résumé des ÉI identifiés dans les versions d'essais cliniques des vaccins contre la COVID-19 autorisés et disponibles.

Réactions locales

La douleur au point d'injection est très courante après l'administration des vaccins contre la COVID-19 actuellement autorisés. Plus de 40 % des sujets vaccinés ont ressenti une douleur au point d'injection. Les rougeurs et les gonflements sont courants ou très courants après l'administration. Un gonflement axillaire localisé et une sensibilité étaient des ÉI sollicités dans le cadre de l'essai clinique du vaccin contre la COVID-19 de Moderna et étaient très fréquents après l'administration de ce vaccin. Les ÉI localisés sont généralement légers ou modérés et se résorbent dans les quelques jours suivant la vaccination. Pour les vaccins à ARNm contre la COVID-19 autorisés, la douleur au point d'injection était légèrement plus fréquente dans les groupes d'âge autorisés plus jeunes, y compris les adolescents de 12 à 15 ans (vaccin contre la COVID-19 de de Pfizer-BioNTech), par rapport aux adultes plus âgés. Pour le vaccin contre la COVID-19 d'AstraZeneca, les réactions locales ont été plus légères et moins fréquentes après la deuxième dose de vaccin que la première dans tous les groupes d'âge. Des fréquences semblables de réactions locales ont été signalées dans l'ensemble des groupes d'âge après l'administration du vaccin de Janssen.

Réactions systémiques

La fatigue, les maux de tête, les douleurs musculaires, les frissons et les douleurs articulaires sont tous très courants après l'administration d'un des vaccins contre la COVID-19 actuellement autorisés. La fièvre était très courante après l'administration de la deuxième dose des vaccins à ARNm contre la COVID-19 et courante après toute dose de vaccins à vecteur viral. Plus du quart des sujets vaccinés ont ressenti des maux de tête ou de la fatigue après avoir reçu l'une ou l'autre dose. Les ÉI systémiques sont généralement d'intensité légère ou modérée et se résorbent dans les quelques jours suivant la vaccination. Pour les vaccins à ARNm contre la COVID-19, les réactions systémiques sont plus fréquentes après la deuxième dose de vaccin et dans les groupes d'âge autorisés plus jeunes, y compris les adolescents de 12 à 15 ans (vaccin contre la COVID-19 de Pfizer-BioNTech). Pour le vaccin contre la COVID-19 d'AstraZeneca, les réactions systémiques sont plus légères et moins fréquentes après la deuxième dose de vaccin comparativement à celles de la première dans tous les groupes d'âge. Les fréquences de réactions systémiques qui ont été signalées après l'administration du vaccin de Janssen étaient semblables d'un groupe d'âge à l'autre.

Évènements indésirables suivant la deuxième dose contre la COVID-19 chez les personnes antérieurement infectées par le SRAS-CoV-2

Il existe des données probantes sur l'innocuité des doses de rappel, à partir d'études observationnelles [25] et cliniques [26][27][28]. La fréquence des ÉI systémiques sollicités et non sollicités chez les personnes antérieurement infectées par le SRAS-CoV-2 était légèrement plus élevée par rapport à la population qui n'avait pas contracté le SRAS-CoV-2, principalement chez les adultes plus jeunes. Toutefois, aucune augmentation de la fréquence des ÉI plus sévères n'a été

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constatée dans cette population. Deux études observationnelles comprenaient moins de 100 patients ayant des symptômes persistants d'infections antérieures du SRAS-CoV-2 (COVID de longue durée). Dans ce sous-groupe, l'administration d'un vaccin à ARNm ou à vecteur viral contre la COVID-19 n'était pas associée à une aggravation des symptômes de COVID-19 de longue durée ni à une réactogénicité accrue après la vaccination.

IV.8.2 Évènements indésirables peu fréquents, rares et très rares

Des ÉI peu fréquents se produisent chez 0,1 % à moins de 1 % des personnes vaccinés. Des ÉI rares et très rares se produisent chez 0,01 % à moins de 0,1 %, respectivement, et chez moins de 0,01 % des sujets vaccinés. La probabilité de détection d'ÉI très rares dans les essais cliniques est faible, compte tenu de la taille de la population des essais et de la durée du suivi; par conséquent, une pharmacovigilance continue est essentielle.

À ce jour, les données disponibles n'indiquent pas que la vaccination des individus n'ayant jamais été infectés par le SRAS-CoV-2 par les vaccins contre la COVID-19 autorisés provoquera une aggravation ou une modification de la maladie en cas d'infection ultérieure par le SRAS-CoV-2 (p. ex., maladie aggravée par le vaccin); toutefois, des études supplémentaires sont nécessaires.

La lymphadénopathie était un évènement sollicité dans les essais cliniques de Moderna mais elle ne l'était pas dans les autres essais de vaccins contre la COVID-19 autorisés (voir l'Annexe E). Elle a rarement été signalée après l'administration des vaccins contre la COVID-19 de Pfizer-BioNTech, d'AstraZeneca et de Janssen.

Aucun autre ÉI sollicité rare ou très rare n'a été signalé à ce jour parmi les participants vaccinés pendant les essais cliniques.

Thrombose et thrombocytopénie suivant l'administration des vaccins à vecteur viral contre la COVID-19

De très rares cas de graves caillots sanguins (à des sites inhabituels comme la CVST, la thrombose veineuse splanchnique et la thrombose artérielle) associés à la thrombocytopénie ont été signalés globalement après l'administration des vaccins à vecteur viral contre la COVID-19. La terminologie de ce syndrome a évolué depuis que le signalement en matière d'innocuité a été détecté. Le Système canadien de surveillance des effets secondaires suivant l'immunisation (SCSESSI) emploie la définition de cas pour le syndrome de thrombose avec thrombocytopénie (STT) [29] afin de détecter ces évènements rares au Canada. Les cas dont le test aux anticorps anti-PF4 (anticorps dirigés contre les complexes du facteur plaquettaire 4 polyanionique) est positif représentent un sous-groupe des événements de STT et sont désignés en médecine clinique sous le nom de thrombocytopénie immunitaire prothrombotique induite par le vaccin (TIPIV) ou de thrombocytopénie thrombotique immunitaire induite par le vaccin (TTIV).

Des déclarations de cas et des séries de cas à l'échelle internationale ont signalé que les cas dont le test aux anticorps anti-PF4 est positif pourraient être associés de manière causale aux vaccins à vecteur viral [30][31][32][33][2][34]. Des données probantes sur l'association entre le STT suivant l'immunisation et l'administration des vaccins à vecteur viral contre la COVID-19 sont en évolution. Toutefois, de multiples systèmes de surveillance à l'échelle internationale ont des données précoces qui pointent systématiquement vers une association entre les vaccins à vecteur adénovirus contre

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la COVID-19 et le SST, y compris aux É.-U., au R.-U. et en Europe. Le mécanisme exact par lequel les vaccins à vecteur viral contre la COVID-19 peuvent déclencher ce syndrome est encore en cours d'investigation mais ces vaccins à vecteur viral semblent déclencher une présentation semblable à la thrombose spontanée induite par l'héparine / thrombose auto-immune induite par l'héparine, où les anticorps dirigés contre les complexes du facteur plaquettaire 4 (PF4) polyanionique suscitent l'activation des plaquettes, ce qui cause une thrombose et une thrombocytopénie [30]. Les caillots associés à la TTIV peuvent être très agressifs et difficiles à traiter [35]. Voir les orientations de Thrombose Canada sur la prise en charge clinique de la TTIV. Ils ne peuvent être gérés de la même façon que les caillots liés aux contraceptifs, à l'immobilité ou aux vols à longue distance, et ont un mécanisme d'action biologique complètement différent.

Les cas de TTIV se produisent généralement entre 4 et 28 jours après l'administration d'un vaccin à vecteur viral contre la COVID-19, mais les patients devraient être suivis jusqu'à 42 jours [36] suivant la vaccination. La fréquence de la TTIV est estimée à 1 cas par 26 000 et à 1 cas par 100 000 personnes ayant reçu une première dose du vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD. Au 1 juin 2021, l'ASPC a estimé le taux de la TTIV au Canada à 1 par 73 000 doses administrées. Toutefois, au fur et à mesure que les recherches se poursuivent, ce taux pourrait s'élever à 1 par 50 000 personnes. Pour des mises à jour sur le nombre de cas de STT et de TTIV au Canada, voir la section sur « les ÉIG et les ÉI non graves signalés » dans la Déclaration des effets secondaires signalés après la vaccination contre la COVID-19 au Canada. La fréquence de la TTIV après l'administration d'une deuxième dose du vaccin d'AstraZeneca se situe actuellement entre 1 par 600 000 et 1 par 750 000 personnes vaccinées avec une deuxième dose, selon des données de surveillance sur l'innocuité des vaccins au R.-U mais la situation continue à évoluer [2]. Le taux de fatalité des cas de TTIV varie également entre les pays et se situe entre 20 et 50 %. De nombreux cas ont été constatés avec une morbidité à long terme grave, y compris des dommages neurologiques. Des signalements de cas de TTIV après l'administration du vaccin de Janssen émergent actuellement des É.-U. En date du 24 mai 2021, 32 cas ont été confirmés après l'administration d'environ 10,2 millions de doses du vaccin de Janssen aux É.-U., et d'autres font l'objet d'une enquête. Pour de plus amples renseignements, voir l'Annexe C, l'Annexe D, et la réponse rapide du CNNI : Utilisation recommandée du vaccin contre la COVID-19 d'AstraZeneca chez les jeunes adultes.

Myocardite ou péricardite suivant l'administration d'un vaccin à ARNm contre la COVID-19

De très rares cas de myocardite (inflammation du muscle cardiaque) et de péricardite (inflammation de la muqueuse autour du cœur) suivant l'administration de vaccins à ARNm contre la COVID-19 [37] ont été signalés au Canada et à l'échelle internationale, notamment en Israël [38], aux É.-U [39] et en Europe [38]. En Israël et aux É.-U., des cas de myocardite et de péricardite ont été signalés le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose [40, 41]. Les données au Canada émergent et la surveillance se poursuit [42].

Il existe de nombreuses causes potentielles de myocardite et de péricardite, y compris des causes infectieuses et non infectieuses. La sévérité de la maladie peut être variable. Les cas de myocardite et de péricardite qui ont été signalés après l'administration d'un vaccin à ARNm contre la COVID-19 à ce jour étaient généralement bénins et les personnes ont tendance à récupérer rapidement. [43-46] Les symptômes peuvent inclure un essoufflement, des douleurs thoraciques ou la sensation d'un rythme cardiaque rapide ou anormal. Les symptômes peuvent être accompagnés de tests anormaux (par exemple, électrocardiogramme, troponines sériques, échocardiogramme).

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Sur la base des cas signalés au niveau international, les renseignements disponibles indiquent que les cas de myocardite et de péricardite après l'administration d'un vaccin à ARNm contre la COVID-19 surviennent :

- plus souvent après la deuxième dose;
- généralement dans la semaine suivant la vaccination;
- plus souvent chez les adolescents et les jeunes adultes;
- plus souvent chez les hommes que chez les femmes.

Dans le cadre des efforts continus en matière d'innocuité des vaccins contre la COVID-19, l'ASPC et Santé Canada surveillent de près la myocardite et la péricardite grâce à des systèmes canadiens de surveillance de l'innocuité passive et active et à la collaboration avec les autorités sanitaires provinciales et territoriales canadiennes, les fabricants et les organismes de réglementation internationaux.

Le CCNI continue à examiner les renseignements au fur et à mesure qu'ils deviennent disponibles et fera les démarches appropriées si nécessaire.

Voir le rapport hebdomadaire sur les ESSI de l'ASPC pour de plus amples renseignements sur le nombre de cas signalés au Canada. Voir également la Déclaration des effets secondaires suivant l'immunisation (ESSI) au Canada et la définition de cas de la myocardite récemment élaborée par la Brighton Collaboration pour de plus amples renseignements sur la préparation et la soumission des déclarations d'ESSI.

Syndrome de fuite capillaire après l'administration du vaccin contre la COVID-19 d'AstraZeneca

De très rares cas de SFC ont été signalés après l'administration du vaccin contre la COVID-19 d'AstraZeneca [2, 3, 38]. Le SFC est une maladie grave très rare qui provoque une fuite de liquide des petits vaisseaux sanguins (capillaires), entraînant un gonflement principalement dans les bras et les jambes, une pression artérielle basse, un épaississement du sang et de faibles taux sanguins d'albumine (une protéine sanguine importante). Les symptômes sont souvent associés à une sensation de faiblesse (attribuable à une pression artérielle basse).

Au Canada, au 18 juin 2021, un cas de SFC avait été confirmé [47] parmi plus de 2 250 000 doses de vaccins d'AstraZeneca/COVISHIELD administrées. Au 27 mai 2021, six cas de SFC chez les personnes ayant reçu le vaccin contre la COVID-19 d'AstraZeneca avaient été examinés par le comité d'évaluation des risques en matière de pharmacovigilance (PRAC) de l'Agence européenne des médicaments (EMA) parmi 78 millions de doses du vaccin contre la COVID-19 d'AstraZeneca administrées au Royaume-Uni (R.-U.) et dans l'Espace économique européen/Union européenne (EEE/UE). Trois des personnes touchées avaient des antécédents de SFC et une est décédée par la suite. Après son examen, le PRAC de l'EMA a conclu que les personnes ayant des antécédents de SFC ne devraient pas recevoir le vaccin contre la COVID-19 d'AstraZeneca.

L'ASPC et Santé Canada surveillent de près le SFC en ce qui concerne le vaccin d'AstraZeneca. Santé Canada travaille en étroite collaboration avec les fabricants pour s'assurer que l'étiquetage reflète les renseignements pertinents [42].

Les cas de SFC après la vaccination contre la COVID-19 au Canada devraient être signalés pour faciliter la surveillance de l'innocuité des vaccins. Voir la Déclaration des effets secondaires suivant

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l'immunisation (ESSI) au Canada pour de plus amples renseignements sur la façon de remplir et de soumettre les déclarations d'ESSI.

Voir la ***Section IV.10 Contre-indications et précautions*** pour de plus amples directives sur le SFC comme une contre-indication au vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD.

IV.8.3 Conseils pour la déclaration des effets secondaires suivant l'immunisation

Les vaccinateurs sont priés de déclarer les ESSI par l'intermédiaire des unités de santé publique locales et de respecter les exigences de déclaration des ESSI propres à leur province ou territoire. En général, tout évènement indésirable grave (ÉIG) (défini comme entraînant une hospitalisation, une invalidité permanente ou un décès) ou inattendu qui est temporellement lié à la vaccination devrait être signalé.

En plus des exigences provinciales ou territoriales en matière de déclaration, la Brighton Collaboration a élaboré une liste d'ÉI d'importance particulière qui présentent un grand intérêt et qui devraient être déclarés; voir le site Web https://brightoncollaboration.us/covid-19/ (en anglais seulement) pour consulter la liste comprenant les définitions.

Il pourrait y avoir d'autres ESSI très rares qui n'ont pas été détectés dans le cadre des essais cliniques jusqu'à présent.

Voir la Section Effets secondaires suivant l'immunisation du GCI, Partie 2 - Sécurité des vaccins pour de plus amples renseignements sur les définitions, l'établissement de rapports, les enquêtes et la gestion, ainsi que sur les évaluations de causalité des ESSI.

Pour de plus amples renseignements sur la réalisation et la soumission de déclarations d'ESSI, voir le site Déclaration de manifestations cliniques inhabituelles à la suite d'une immunisation au Canada.

Voir le rapport hebdomadaire de l'ASPC sur les effets secondaires suivant l'immunisation contre la COVID-19 au Canada.

IV.9 Populations spéciales

Les populations suivantes ont été exclues des essais cliniques sur les vaccins contre la COVID-19 ou y ont été inclues en petit nombre. Toutefois, les données en conditions réelles sur l'utilisation des vaccins contre la COVID-19 dans ces populations s'accumulent. Le CCNI continue à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.

Personnes antérieurement infectées par le SRAS-CoV-2

Dans des études qui ont rapporté des réponses immunitaires chez les personnes ayant contracté antérieurement le SRAS-CoV-2 [48][26][49][50][51][52], les concentrations d'anticorps en anti-S et en anti-RBD IgG, les titres neutralisants et les réponses cellulaires B et T après l'administration de la première dose, étaient comparables à ceux observées chez les personnes qui n'avaient pas été infectées par le SRAS-CoV-2 après l'administration de la deuxième dose. Les réactions à anticorps de liaison et de neutralisation élevées ont été observées chez les personnes antérieurement

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infectées symptomatiques ou asymptomatiques par rapport aux sujets vaccinés qui n'avaient pas été infectés. Ces résultats rejoignaient ceux qui avaient été constatés par les chercheurs de l'étude RECOVER [52]. Toutefois, en l'absence d'un corrélat de protection établi, il n'est pas possible de déterminer l'importance de ces résultats par rapport au niveau de protection contre la réinfection.

Personnes immunodéprimées en raison d'une maladie ou d'un traitement

Des données probantes sur l'innocuité de la vaccination contre la COVID-19 chez ces personnes émergent. Les données sur l'innocuité chez les personnes immunodéprimées, y compris celles qui reçoivent un traitement immunosuppresseur, étaient disponibles à partir d'études observationnelles chez les receveurs de greffe d'organe solide, les patients atteints du cancer et les personnes atteintes de maladies inflammatoires chroniques [53][54][55][56][57][58][59][60][61][62][63][64][65][66]. La fréquence et la sévérité des ÉI après l'administration d'un vaccin à ARNm contre la COVID-19 dans ces populations étaient comparables à celles des personnes non-immunodéprimées dans le cadre de ces études et à ce qui avait été indiqué dans les essais cliniques. Les données sur l'innocuité dans ces populations après l'administration d'un vaccin à vecteur viral ne sont pas disponibles.

L'efficacité potentielle et l'efficacité réelle des vaccins contre la COVID-19 chez les populations immunodéprimées sont actuellement inconnues, mais les données probantes sur la diminution de la réponse immunitaire émergent. Les données sur l'immunogénicité chez les personnes immunodéprimées, y compris celles qui reçoivent un traitement immunosuppresseur, étaient disponibles à partir d'études observationnelles chez les receveurs de greffe d'organe solide, les patients atteints du cancer et les personnes atteintes de maladies inflammatoires chroniques qui recevaient un traitement immunosuppresseur [67][68][69][60][59][61][70][71][72][73][74][64][75][66][76][77][78][79][80][55][81][57][58, 82]. Les participants à l'étude ont montré des réponses immunitaires diminuées et retardées aux vaccins à ARNm contre la COVID-19 ou au vaccin contre la COVID-19 d'AstraZeneca. Le type de traitement immunosuppresseur ou d'affection a influé sur la réponse immunitaire aux vaccins contre la COVID-19, entraînant dans certains cas un manque de réponses humorales et cellulaires ou des niveaux diminués chez les personnes qui ont développé des réponses comparativement à des contrôles sains. Vu le nombre limité de participants et le manque de corrélat de protection immunologique contre l'infection par le SRAS-CoV-2, il y a des limites à interpréter l'importance de ces résultats. Les mêmes principes généraux peuvent s'appliquer chez les personnes atteintes d'une maladie rénale chronique sous hémodialyse (pour qui il existe de solides données probantes sur un risque accru de mortalité lié à la COVID-19), puisque les personnes ayant une fonction rénale altérée ont une réponse moins qu'optimale à la vaccination [83][84][64][85][77][76][86][87].

Personnes ayant une maladie auto-immune

Les données émergentes sur l'innocuité à partir d'études observationnelles chez les personnes ayant une maladie auto-immune indiquent que la fréquence et la sévérité des ÉI dans cette population sont comparables à celles des personnes qui ne souffrent pas de maladie auto-immune et à ce qui a été reporté dans les essais cliniques [53][54][55][56][57, 58][94]. L'apparition d'une nouvelle maladie auto-immune ou l'exacerbation de la maladie après l'administration des vaccins à ARNm contre la COVID-19 était rare ou comparable à l'incidence de fond de ces évènements dans la population générale, Des données sur l'innocuité au sein de cette population après l'administration d'un vaccin à vecteur viral ne sont pas disponibles.

COVID-19

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L'efficacité potentielle et l'efficacité réelle des vaccins contre la COVID-19 chez les personnes ayant une maladie auto-immune sont inconnues mais les données sur l'immunogénicité émergent. Des données étaient disponibles à partir d'études observationnelles dans lesquelles les participants ont reçu des vaccins à ARNm contre la COVID-19 ou des vaccins contre la COVID-19 d'AstraZeneca [80][55][81][57] [82][58]. Les réponses immunitaires étaient plus faibles seulement chez les participants qui recevaient également un traitement immunosuppresseur. Vu le nombre limité de participants et le manque de corrélat de protection immunologique contre une infection par le SRAS-CoV-2, il y a des limites à interpréter l'importance de ces résultats.

Personnes enceintes ou allaitantes

Des données probantes sur l'innocuité et l'immunogénicité des vaccins contre la COVID-19 chez les personnes enceintes et allaitantes émergent. Les études précliniques sur l'innocuité des vaccins contre la COVID-19 à partir d'études de toxicité sur le développement et la reproduction des animaux n'ont pas identifié de préoccupations concernant la reproduction femelle, le développement fœtal/embryonnaire ou le développement postnatal après l'administration du vaccin contre la COVID-19 de Moderna avant ou pendant la grossesse [95]. Un rapport présenté à l'EMA n'a aussi indiqué aucun ÉI en ce qui concerne la fertilité, la grossesse, le développement embryonnaire/fœtal ou le développement postnatal (jusqu'au jour 21) dans le cadre d'études sur des rats ayant une dose complète du vaccin contre la COVID-19 de Pfizer-BioNTech [96]. Une revue par la Food and Drug Administration (FDA) sur une étude chez les lapins ayant reçu le vaccin contre la COVID-19 de Janssen à deux fois la dose humaine avant ou pendant la gestation ont également conclu qu'il n'y avait aucun ÉI lié à la reproduction femelle, au développement fœtal/embryonnaire ou au développement postnatal [97]. AstraZeneca a mené une étude préliminaire DART (Developmental and Reproductive Toxicity) chez 32 souris femelles ayant reçu le vaccin avant et pendant la gestation et n'a trouvé aucun effet de la reproduction femelle, de la survie ou du développement du fœtus ou des petits. Leur étude principale DART chez les souris est en cours [98].

Une analyse des données recueillies à partir des registres de vaccination contre la COVID-19 à l'échelle internationale à ce jour n'a pas révélé de signalement en matière d'innocuité maternelle ou néonatale et des analyses préliminaires de plus de 35 000 personnes enceintes aux É.-U. qui ont reçu un vaccin à ARNm contre la COVID-19 n'a pas indiqué de signalement évident en matière d'innocuité [99]. Dans une petite étude de cohorte, l'ARNm des vaccins contre la COVID-19 étaient indétectables dans le lait maternel 4-48 heures après la vaccination [100].

Les données probantes émergentes suggèrent que la vaccination à ARNm contre la COVID-19 pendant la grossesse est aussi immunogène et donne lieu à des titres d'anticorps comparables à ceux des personnes qui ne sont pas enceintes [101][102][103]. La réponse humorale IgG maternelle aux vaccins à ARNm contre la COVID-19 passe du placenta au fœtus, entraînant ainsi un titre d'anticorps important et potentiellement protecteur à la circulation sanguine néonatale une semaine suivant l'administration de la deuxième dose [104][101][105, 106]. Des études observationnelles montrent systématiquement que les anti-S IgG et IgA sont présents dans le lait maternel au moins pendant 6 semaines après l'administration des vaccins à ARNm auprès des personnes enceintes ou allaitantes [107][108][109][110].

IV.10 Contre-indications et précautions

De rares réactions anaphylactiques ont été signalées à la suite de l'immunisation par des vaccins à ARNm contre la COVID-19.

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Le Tableau 4 énumère les ingrédients non médicinaux potentiels des vaccins contre la COVID-19 autorisés et disponibles qui ont été associés à des réactions allergiques dans d'autres produits. Ces réactions se sont rarement produites et elles ont varié de légères réactions cutanées à l'anaphylaxie. L'anaphylaxie est une réaction allergique rare, sévère et potentiellement mortelle qui se manifeste généralement rapidement. Elle touche plusieurs systèmes organiques et peut progresser rapidement. Les symptômes et signes d'anaphylaxie peuvent inclure, sans s'y limiter : l'urticaire généralisée, une respiration sifflante, une enflure de la bouche, de la langue et de la gorge, des difficultés respiratoires, des vomissements, de la diarrhée, de l'hypotension, une diminution du niveau de conscience et un état de choc. Il est important de noter que d'autres réactions moins graves peuvent imiter des réactions allergiques (p. ex., la syncope vasovagale) et la vaccination n'est pas contre-indiquée dans ces cas.

Voir le site Anaphylaxie et autres réactions aiguës après la vaccination, Partie 2 – La sécurité des vaccins du GCI pour de plus amples renseignements sur la gestion de l'anaphylaxie après la vaccination.

Tableau 4. Ingrédients des vaccins contre la COVID-19 autorisés et disponibles qui ont été associés à des réactions allergiques dans d'autres produits

Produit de vaccination	Allergène potentiel inclus dans le vaccin ou son contenant	Autres produits dans lesquels l'allergène peut être présent*
Vaccin contre la COVID-19 de Pfizer-BioNTech	Polyéthylèneglycol (PEG) [a,b,c]	Médicaments en vente libre (p. ex., sirop contre la toux, laxatifs) et médicaments sur ordonnance, produits de préparation intestinale médicale pour la coloscopie, produits de soins de la peau, produits de remplissage dermique, cosmétiques, solutions d'entretien des lentilles de contact, produits tels que le gel pour ultrasons[d]
Vaccin contre la COVID-19 de Moderna	PEG [a, b, c]	Médicaments en vente libre (p. ex., sirop contre la toux, laxatifs) et médicaments sur ordonnance, produits de préparation intestinale médicale pour la coloscopie, produits de soins de la peau, produits de remplissage dermique, cosmétiques, solutions d'entretien des lentilles de contact, produits tels que le gel pour ultrasons[d]
	Trométhamine[e] (trométamol ou Tris)	Composant dans les produits de contraste, les médicaments oraux et parentéraux

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Produit de vaccination	Allergène potentiel inclus dans le vaccin ou son contenant	Autres produits dans lesquels l'allergène peut être présent*
Vaccin contre la COVID-19 d'AstraZeneca	Polysorbate 80[c]	Préparations médicales (p. ex., huiles vitaminées, comprimés et agents anticancéreux), cosmétiques[d,f]
Vaccin contre la COVID-19 de Janssen	Polysorbate 80[c]	Préparations médicales (p. ex., huiles vitaminées, comprimés et agents anticancéreux), cosmétiques[d,f]

Note : Cette liste de produits n'est pas exhaustive.

[a] Les médicaments qui contiennent du PEG sont décrits dans Stone CA, *et coll.*, DOI :10.1016/j.jaip. 2018.12.003.

[b] Une revue des réactions d'hypersensibilité de type immédiat au PEG est disponible dans Wenande *et coll.*, DOI : 10.1111/cea.12760.

[c] Il existe un potentiel d'hypersensibilité croisée entre le PEG et les polysorbates.

[d] Le PEG peut également être présent dans les aliments ou les boissons, mais les réactions allergiques au PEG dans les aliments ou les boissons n'ont pas été documentées.

[e] Un cas d'anaphylaxie à la tromethamine a été décrit (Lukawska *et coll.*, DOI : 10.1016/j.jaip.2018.08.035).

[f] Des cas d'anaphylaxie au polysorbate 80 ont été décrits (Badiu *et coll.*, DOI : 10.1136/bcr.02.2012.5797, Palacios Castaño *et coll.*, DOI : 10.18176/jiaci.0109).

De rares cas de TTIV ont été signalés suivant l'administration des vaccins à vecteur viral contre la COVID-19. Des recherches sont en cours et les recommandations seront mises à jour au fur et à mesure que les données probantes seront disponibles. Pour de plus amples renseignements, voir l'Annexe C et l'Annexe D.

Contre-indications

Anaphylaxie et allergies à un vaccin contre la COVID-19

Un vaccin contre la COVID-19 autorisé ne devrait pas être proposé systématiquement aux personnes ayant des antécédents de réaction allergique sévère (p. ex., anaphylaxie) après l'administration antérieure d'un vaccin contre la COVID-19 utilisant une plateforme similaire (ARNm ou vecteur viral). Si une évaluation des risques juge que les avantages l'emportent sur les risques pour l'individu; et si le consentement éclairé est fourni, un vaccin contre la COVID-19 autorisé utilisant une plateforme différente peut être envisagé pour une réimmunisation (c'est-à-dire que les individus ayant reçu un vaccin à ARNm post-anaphylactique peuvent se voir proposer un vaccin à vecteur viral et les individus ayant reçu un vaccin à vecteur post-anaphylactique viral peuvent se voir proposer un vaccin à ARNm). Si une vaccination avec une plateforme différente est proposée, les personnes devraient être observées pendant au moins 30 minutes après la vaccination.

Un vaccin contre la COVID-19 autorisé ne devrait pas être systématiquement proposé aux personnes qui sont allergiques à l'un des composants du vaccin contre la COVID-19 spécifique ou à son contenant. Pour obtenir une liste complète des composants de chaque vaccin contre la COVID-19 autorisé et de son contenant, veuillez consulter le dépliant du produit correspondant ou les informations contenues dans la monographie du produit disponible sur le site Base de données sur les produits pharmaceutiques de Santé Canada.

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Thrombose et thrombocytopénie après la vaccination

Les patients ayant subi une thrombose artérielle ou veineuse avec une thrombocytopénie suivant l'administration d'un vaccin à vecteur viral contre la COVID-19 ne devrait pas recevoir une deuxième dose d'un vaccin à vecteur viral contre la COVID-19.

Syndrome de fuite capillaire

Par mesure de précaution à la suite des cas à l'échelle internationale qui ont été signalés, les personnes ayant des antécédents de SFC ne devraient pas recevoir le vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD.

Précautions

Hypersensibilité et allergies

Si une évaluation des risques juge que les avantages l'emportent sur les risques potentiels pour l'individu; et si le consentement éclairé est donné, la vaccination peut être envisagée chez les personnes présentant des réactions allergiques immédiates légères à modérées (définies comme étant limitées dans l'étendue des symptômes et l'implication des systèmes organiques ou même localisées au site d'administration) après une dose précédente de vaccins contre la COVID-19 autorisés. Une évaluation par un médecin ou une infirmière ayant une expertise en matière de vaccination peut être justifiée avant la réimmunisation. Dans la plupart des cas, la réaction anaphylactique se manifeste dans les 30 minutes qui suivent l'administration du vaccin. Par conséquent, si l'on opte pour la vaccination, une période prolongée d'observation post-vaccinale d'au moins 30 minutes devrait être prévue pour les personnes susmentionnées.

Les personnes présentant une réaction allergique sévère avérée (p. ex., anaphylaxie) à un traitement injectable non lié à un composant des vaccins contre la COVID-19 autorisés (p. ex., vaccins ou traitements intramusculaires, intraveineux ou sous-cutanés) peuvent être vaccinées systématiquement et n'ont pas besoin d'être évaluées. Dans la plupart des cas, la réaction anaphylactique se manifeste dans les 30 minutes qui suivent l'administration du vaccin. Par conséquent, une période d'observation post-vaccinale prolongée de 30 minutes devrait être prévue pour les personnes susmentionnées.

Les personnes soupçonnées de souffrir d'une allergie à un ingrédient du vaccin (c.-à-d. le PEG) qui n'a pas encore été prouvée peuvent être systématiquement vaccinées et n'ont pas besoin d'une évaluation spécifique concernant cette allergie suspectée. La majorité des cas d'anaphylaxie à un vaccin se déclenche dans les 30 minutes suivant l'administration du vaccin. Une période d'observation prolongée post-vaccination de 30 minutes devrait donc être prévue à cette fin.

Les personnes ayant des antécédents d'allergie non liés à un composant des vaccins contre la COVID-19 autorisés ou à une autre thérapie injectable (p. ex., aliments, médicaments, venin d'insecte ou allergènes environnementaux) peuvent recevoir les vaccins contre la COVID-19 sans aucune précaution particulière. Les personnes devraient faire l'objet d'une observation pendant au moins 15 minutes après la vaccination.

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Maladie aiguë

La vaccination des individus qui pourraient être actuellement infectés par le SRAS-CoV-2 ne devrait pas avoir d'effet néfaste sur la maladie. Toutefois, la vaccination devrait être retardée chez les individus symptomatiques atteints d'une infection par le SRAS-CoV-2 confirmée ou soupçonnée, ou chez ceux qui présentent des symptômes respiratoires, afin d'éviter d'attribuer toute complication découlant de l'infection par le SRAS-CoV-2 à des ESSI liés à la vaccination et de réduire au minimum le risque de transmission de la COVID-19 dans une clinique ou un centre de vaccination. Si des symptômes sont détectés chez une personne à son arrivée sur les lieux, il faudrait lui dire de suivre les mesures de santé publique locales en vigueur.

Par mesure de précaution et compte tenu de la nécessité de pouvoir surveiller les ÉI du vaccin contre la COVID-19 sans risque de confusion avec les symptômes de la COVID-19 ou d'autres maladies coexistantes, il faudrait attendre que tous les symptômes d'une maladie aiguë aient disparu avant d'administrer un vaccin contre la COVID-19 autorisé.

Hématologie

Chez les individus atteints d'un trouble hémorragique, celui-ci devrait être pris en charge avant l'immunisation afin de réduire au minimum le risque d'hémorragie. Les individus qui reçoivent une anticoagulation à long terme ne sont pas considérés comme étant exposés à un risque plus élevé de complications hémorragiques après une immunisation et peuvent être vaccinés de façon sécuritaire sans interrompre leur traitement par anticoagulants.

Thrombose et thrombocytopénie

Les personnes qui ont subi une CVST antérieure avec thrombocytopénie ou thrombocytopénie induite par l'héparine (TIH) ne devraient recevoir un vaccin à vecteur viral contre la COVID-19 que si les avantages potentiels l'emportent sur les risques potentiels. Un autre vaccin contre la COVID-19 devrait leur être offert.

Toute personne recevant un vaccin à vecteur viral contre la COVID-19 autorisé devrait être informée des risques liés à la TTIV, et être avisée de consulter immédiatement un médecin si elle développe des symptômes de TTIV. Les symptômes peuvent comprendre : l'essoufflement, la douleur à la poitrine, l'œdème des jambes ou douleurs aux jambes ou la douleur abdominale persistante après la vaccination. De plus, toute personne qui souffre de symptômes neurologiques après la vaccination, y compris l'apparition soudaine de maux de tête sévères, persistants ou aggravants, de vision trouble, de confusion ou de crise, ou qui souffre d'ecchymoses à l'épiderme ou de pétéchies inhabituelles ailleurs qu'au site d'injection quelques jours après la vaccination, devrait consulter immédiatement un médecin.

Myocardite et/ou péricardite

La surveillance de l'innocuité post-commercialisation des vaccins à ARNm contre la COVID-19 a révélé une fréquence accrue de myocardite et de péricardite à l'échelle internationale, signalées très rarement mais le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose [40, 41]. L'association de la myocardite et de la péricardite avec la vaccination à ARNm et un mécanisme pour l'inflammation restent à l'étude.

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Par mesure de précaution, la deuxième dose de la série de vaccins à ARNm contre la COVID-19 devrait être reportée chez les personnes qui souffrent de myocardite ou de péricardite suivant la première dose d'un vaccin à ARNm contre la COVID-19 jusqu'à ce que de plus amples renseignements soient disponibles. Le CCNI continuera à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.

Toute personne recevant un vaccin à ARNm contre la COVID-19 autorisé devrait être informée du risque de myocardite (inflammation du muscle cardiaque) et de péricardite (inflammation de la muqueuse autour du cœur) et invitée à consulter un médecin si elle développe des symptômes, y compris douleur thoracique, essoufflement ou palpitations.

Les professionnels de la santé devraient tenir compte de la myocardite et/ou de la péricardite dans leur évaluation si des symptômes cliniquement compatibles (douleur thoracique, essoufflement, palpitations) sont présents chez le patient après la deuxième dose d'un vaccin à ARNm contre la COVID-19 mais ils doivent être étudiés, peu importe le moment entre la vaccination et l'apparition des symptômes. Les investigations incluent l'électrocardiogramme, les troponines sériques et l'échocardiogramme avec des résultats anormaux fréquents d'électrocardiogramme et des niveaux élevés de troponine. La consultation d'un cardiologue, d'un spécialiste des maladies infectieuses, d'un spécialiste en médecine interne et/ou d'un rhumatologue peut être souhaitable pour aider à cette évaluation, en particulier pour étudier les nombreuses causes potentielles de myocardite et/ou de péricardite. Les investigations peuvent comprendre des tests diagnostiques pour l'infection aiguë par la COVID-19 (p. ex., tests PCR), une infection antérieure par le SRAS-CoV-2 (p. ex., détection d'anticorps de nucléocapside du SRAS-CoV-2) et la prise en compte d'autres étiologies infectieuses ou non infectieuses potentielles, y compris des affections auto-immunes.

Voir les Contre-indications et précautions du GCI, Partie 2 – Innocuité des vaccins pour de plus amples renseignements généraux.

IV.11 Interactions médicamenteuses

Aucune étude sur les interactions médicamenteuses n'a été réalisée à ce jour.

Pour de plus amples renseignements sur les interactions potentielles avec des produits contenant des anticorps anti-SRAS-CoV-2, voir la Section IV.11 Produits sanguins, immunoglobulines humaines et moment de l'immunisation, dans la présente déclaration.

Test cutané à la tuberculine ou test de libération d'interféron gamma (TLIG)
Il existe un risque théorique que les vaccins à ARNm ou à vecteur viral puissent affecter temporairement l'immunité à médiation cellulaire, entraînant des résultats faussement négatifs au test cutané à la tuberculine (TCT) ou au test de libération d'interféron gamma (TLIG). Si un TCT ou un TLIG est nécessaire, il devrait être réalisé avant la vaccination ou au moins 4 semaines après la réception du vaccin. Les vaccins contre la COVID-19 peuvent être administrés à tout moment après l'administration du TCT.

Dans les cas où une occasion de réaliser le TCT ou le TLIG pourrait être manquée, le test ne devrait pas être retardé, car il s'agit de considérations théoriques. Toutefois, il peut être prudent de refaire les tests (au moins 4 semaines après la vaccination) des personnes dont les résultats sont négatifs et pour lesquelles il existe une suspicion élevée d'infection tuberculeuse, afin d'éviter de manquer des cas en raison de résultats potentiellement faux négatifs.

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IV.12 Produits sanguins, immunoglobulines humaines et moment de l'immunisation

Le CCNI recommande que les vaccins contre la COVID-19 ne soient pas administrés simultanément avec des anticorps monoclonaux ou du plasma de convalescents.

À ce jour, il n'y a pas suffisamment de données probantes sur la réception concomitante d'un vaccin contre la COVID-19 et d'anticorps monoclonaux anti-SRAS-CoV-2 ou de plasma de convalescents aux fins de traitement ou de prévention. Par conséquent, le moment de l'administration et l'interférence potentielle entre ces deux produits sont actuellement inconnus. L'administration rapprochée de ces produits peut entraîner une diminution de l'efficacité réelle d'un vaccin contre la COVID-19 ou des anticorps monoclonaux anti-SRAS-CoV-2, car de tels anticorps ont une grande affinité pour la protéine de spicule exprimée par les vaccins, ce qui peut entraver la production d'anticorps stimulée par le vaccin.

Dans un contexte de post-exposition, on devrait obtenir l'opinion d'experts cliniques pour la gestion au cas par cas de l'administration d'anticorps monoclonaux anti-SRAS-CoV-2 après la réception du vaccin contre la COVID-19, en prenant en considération le risque d'exposition et le risque de cas sévère de la COVID-19 chez l'individu.

À ce jour, il n'y a pas non plus suffisamment de données probantes sur la réception d'un vaccin contre la COVID-19 et d'anticorps monoclonaux quelconques ou de plasma de convalescents aux fins de traitement ou de prévention d'une maladie autre que la COVID-19. Par conséquent, le moment de l'administration et l'interférence potentielle entre ces deux produits sont actuellement inconnus, et on devrait consulter un spécialiste clinique au cas par cas.

V. RECOMMANDATIONS

À la suite de l'examen approfondi des données probantes disponibles résumées ci-dessus et de l'évaluation systématique des facteurs d'éthique, d'équité, de faisabilité et d'acceptabilité à prendre en considération à l'aide du cadre ÉÉFA [5] résumé dans le document Orientations préliminaires sur les principales populations à immuniser en priorité contre la COVID-19 du CCNI, ce dernier formule les recommandations éclairées suivantes pour la prise de décision au niveau des programmes de santé publique concernant l'utilisation efficace et équitable des vaccins contre la COVID-19 autorisés et disponibles au Canada.

Le CCNI continuera à surveiller de près les nouveautés scientifiques liées à la COVID-19 et aux vaccins contre la COVID-19, ainsi que les activités de pharmacovigilance sur les vaccins en cours, et mettra à jour ses recommandations si nécessaire.

Veuillez noter :

- Une *recommandation forte* s'applique à la plupart des populations/personnes et devrait être suivie, à moins qu'il n'existe une justification claire et convaincante d'utiliser une autre approche.
- Une *recommandation discrétionnaire* peut être offerte pour certaines populations/personnes dans certaines circonstances. D'autres approches peuvent être acceptables.

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Voir le Tableau 6 pour des explications plus détaillées sur la force des recommandations du CCNI.

RECOMMANDATIONS SUR LES VACCINS CONTRE LA COVID-19 AUTORISÉS ET DISPONIBLES

Ces recommandations s'appliquent uniquement aux vaccins contre la COVID-19 actuellement autorisés pour utilisation au Canada (vaccin contre la COVID-19 de Pfizer-BioNTech; vaccin contre la COVID-19 de Moderna; vaccin contre la COVID-19 d'AstraZeneca; vaccin contre la COVID-19 de Janssen). En tenant compte de ces recommandations et aux fins de la mise en œuvre de programmes financés par les fonds publics, les provinces et territoires peuvent prendre en compte les facteurs programmatiques (p. ex., contextes logistiques et opérationnels, ressources) et l'épidémiologie locale (p. ex., transmission des VP du SRAS-CoV-2).

1. **Le CCNI recommande de préférence de proposer une série complète d'un vaccin à ARNm contre la COVID-19 aux personnes appartenant au groupe d'âge autorisé qui ne présentent pas de contre-indications au vaccin.**
   (*Forte recommandation du CCNI*)

2. **Le CCNI recommande qu'un vaccin à vecteur viral contre la COVID-19 soit proposé aux personnes appartenant au groupe d'âge autorisé et qui ne présentent pas de contre-indications au vaccin pour initier une série lorsque d'autres vaccins contre la COVID-19 autorisés sont contre-indiqués ou inaccessibles. Le consentement éclairé devrait inclure une discussion sur les risques et les symptômes de la TTIV, ainsi que sur la nécessité de consulter immédiatement un médecin en cas d'apparition de symptômes.**
   (*Recommandation discrétionnaire du CCNI*)

Voir le Tableau 5 pour un résumé des données probantes et des facteurs que les administrations devraient prendre en compte lors de la mise en œuvre des programmes de vaccination contre la COVID-19.

Sommaire des données probantes et justification :

- La pandémie de COVID-19 a provoqué une morbidité et une mortalité importantes, ainsi que des perturbations sociales et économiques. Le programme d'immunisation contre la COVID-19 devrait être déployé de la manière la plus efficace, la plus efficiente et la plus équitable possible.
- Les vaccins à ARNm contre la COVID-19 sont autorisés chez les personnes âgées de 12 ans et plus (vaccin contre la COVID-19 de Pfizer-BioNTech) ou de 18 ans et plus (vaccin contre la COVID-19 de Moderna). L'utilisation des vaccins à vecteur viral non réplicatif est autorisée au Canada pour les personnes âgées de 18 ans et plus (vaccin contre la COVID-19 d'AstraZeneca, vaccin contre la COVID-19 de Janssen).
- Pour tous les vaccins contre la COVID-19 actuellement autorisés et disponibles pour utilisation, une série complète compte deux doses, sauf pour le vaccin de Janssen qui est autorisé en une seule dose.
- On peut consulter le Tableau 1 sur les facteurs de risque liés au risque accru de complications sévères attribuables à la COVID-19 et au risque accru d'exposition à la COVID-19. Pour de plus amples renseignements sur le séquençage des principales populations, y compris une analyse détaillée des facteurs d'éthique, d'équité, de faisabilité et d'acceptabilité, voir les orientations du CCNI sur les principales populations à immuniser en priorité contre la COVID-19.

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Vaccins à ARNm contre la COVID-19

- Les données d'essais cliniques disponibles à ce jour ont montré que les vaccins à ARNm contre la COVID-19 actuellement autorisés sont très efficaces (94 % ou plus pour prévenir la COVID-19 symptomatique confirmée à court terme, à partir d'une ou deux semaines après avoir reçu la série complète de deux doses.
- L'efficacité potentielle la plus élevée et la réponse immunitaire maximale ont été observées après la deuxième dose. L'efficacité potentielle de la série de deux doses a été constante dans tous les groupes d'âge.
- Les estimations de l'efficacité réelle du vaccin de Pfizer-BioNTech étaient comparables dans les pays où la souche prédominante en circulation était le VP B.1.1.7 (alpha). Des données probantes émergentes laissent croire que le vaccin de Pfizer-BioNTech est efficace à 33,2 % après la première dose et à 87,9 % après la deuxième dose contre les VP B.1.617.2 (delta).
- Les ÉI locaux et systémiques étaient généralement moins fréquents chez les adultes âgés (de ≥56 ans et plus dans l'essai clinique de Pfizer-BioNTech et de ≥65 et plus dans l'essai clinique de Moderna).
- Les vaccins à ARNm autorisés sont aussi sûrs et efficaces chez les personnes présentant une ou plusieurs comorbidités (p. ex., indice de masse corporelle de ≥30 kg/m^2 ou plus, maladie pulmonaire chronique, diabète sucré, maladie cardiaque).

Le consentement éclairé pour les vaccins à ARNm contre la COVID-19 devrait inclure des renseignements sur les très rares cas de myocardite ou de péricardite dans la semaine suivant l'administration d'un vaccin à ARNm

- Des rapports de surveillance de l'innocuité post-commercialisation de myocardite et de péricardite suivant l'administration des vaccins à ARNm ont été signalés le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose [40, 41].
- La majorité des cas sont bénins et les personnes ont tendance à récupérer rapidement.
- Toute personne recevant un vaccin à ARNm devrait être informée du risque de myocardite et de péricardite et être invitée à consulter un médecin si elle développe des symptômes, notamment un essoufflement, des douleurs thoraciques ou la sensation d'un rythme cardiaque rapide ou anormal.
- Par mesure de précaution, la deuxième dose de la série de vaccins à ARNm contre la COVID-19 devrait être reportée chez les personnes qui souffrent de myocardite ou de péricardite comme un ÉI suivant la première dose d'un vaccin à ARNm contre la COVID-19 jusqu'à ce que de plus amples renseignements soient disponibles. Le CCNI continuera à surveiller les données probantes et à mettre à jour les recommandations si nécessaire.
- Le consentement éclairé devrait également inclure une discussion sur le risque personnel de la personne de contracter la COVID-19 sévère (voir le Tableau 1), le risque d'infection et l'épidémiologie locale (y compris la circulation des VP), les complications de la COVID-19 (qui peuvent inclure la myocardite et la péricardite) et la protection offerte par la vaccination contre la COVID-19.
    - La vaccination des adolescents et des jeunes adultes est recommandée, car les avantages de la vaccination pour prévenir la COVID-19, y compris les VP, l'emportent sur les très rares cas de myocardite et de péricardite.
    - Les personnes âgées de 12 à 24 ans représentent environ 15 % de la population canadienne [111], et de même, ce groupe d'âge constitue environ 18 % des cas cumulatifs de COVID-19 signalés à l'échelle nationale. Toutefois, avec le nombre de personnes âgées qui ont été vaccinées contre la COVID-19, la proportion

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relative des cas de COVID-19 a augmenté chez les groupes d'âge plus jeunes. Contrairement aux populations plus âgées, ce groupe d'âge représente moins de 2 % des cas de COVID-19 entraînant une hospitalisation, moins de 2 % des cas de COVID-19 admis à l'USI et moins de 0,1 % des décès attribuables à la COVID-19 [112].

- Certaines personnes présentent un risque accru d'hospitalisation et de mortalité à cause de la COVID-19 (voir le Tableau 1). Une revue rapide mise à jour des facteurs de risque de maladie sévère menée par ARCHE a révélé une certitude modérée des données probantes d'une augmentation de 2 fois ou plus des hospitalisations chez les personnes de 21 ans et moins atteintes de 2 maladies chroniques ou plus (par rapport à aucune maladie chronique) [7].
- Il existe des données probantes émergentes qui indiquent que les vaccins à ARNm offrent une bonne protection contre l'infection par le VP B.1.617.2 (delta) après la deuxième dose et une très bonne protection contre l'hospitalisation après la première dose.
- Dans des essais cliniques, les vaccins à ARNm contre la COVID-19 se sont révélés immunogènes et efficaces pour prévenir la maladie symptomatique chez les adolescents et les jeunes adultes. Les essais cliniques ont démontré un profil d'innocuité similaire à celui observé dans les groupes plus âgés.

Vaccins contre la COVID-19 d'AstraZeneca

- Les données probantes combinées des essais cliniques et des études d'observation disponibles à ce jour ont montré que le vaccin d'AstraZeneca COVID-19 à vecteur viral actuellement autorisé offre une protection chez les adultes de 18 ans et plus contre la COVID-19 symptomatique et l'hospitalisation après avoir reçu au moins une dose.
  - Les données actuelles tirées des essais cliniques ont montré que le vaccin contre la COVID-19 d'AstraZeneca offre une efficacité potentielle modérée contre la COVID-19 symptomatique confirmée de 62 % chez les 18-64 ans. L'efficacité potentielle d'une série de deux doses s'est élevée à environ 82 % lorsque l'intervalle entre les doses était de 12 semaines ou plus. Chez les adultes de 65 ans et plus, les données observationnelles du R.-U. sur l'efficacité réelle du vaccin après l'administration d'une dose ont révélé une baisse des risques de maladie symptomatique et d'hospitalisation.
  - L'efficacité potentielle la plus élevée avec le schéma autorisé du vaccin d'AstraZeneca COVID-19 a été observée dans les groupes d'essais cliniques qui avaient un intervalle plus long entre les doses. Les essais cliniques suggèrent que l'efficacité potentielle du vaccin augmente avec des intervalles prolongés entre la première et la deuxième dose du vaccin, une réduction maximale du risque de maladie symptomatique étant observée à 12 semaines ou plus après la primovaccination.
- Les données laissent croire que le vaccin contre la COVID-19 d'AstraZeneca a une efficacité potentielle de 74,6 % contre le VP B.1.1.7 (alpha) (par rapport à 84,1 % contre la souche non attribuable au variant B.1.1.7 [alpha]). Les données publiées suggèrent une efficacité potentielle de 10,4 % face à la maladie légère à modérée attribuable au VP B.1.351 (béta). Des données émergentes laissent croire que le vaccin d'AstraZeneca est efficace à 32,9 % après une dose et à 59,8 % après la deuxième dose contre le VP B.1.617.2 (delta).

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- Dans les essais cliniques, la majorité des ÉI locaux et systémiques du vaccin d'AstraZeneca COVID-19 étaient légers et transitoires et ne différaient pas en fonction de la dose administrée ou de l'âge.
- Des cas très rares mais graves de caillots sanguins, y compris la thrombose du sinus veineux cérébral, avec une thrombocytopénie concomitante, ont été signalés dans le monde entier après l'utilisation post-homologation de vaccins à vecteur viral contre la COVID-19. Le mécanisme exact par lequel ces vaccins peuvent déclencher une thrombose avec thrombocytopénie est encore à l'étude. Le taux de létalité se situe généralement entre 20 et 50 %.
- Le vaccin contre la COVID-19 d'AstraZeneca est tout aussi efficace chez les personnes souffrant d'une ou plusieurs affections médicales légères à modérées et contrôlées (p. ex., maladie cardiovasculaire, maladie respiratoire, diabète, indice de masse corporelle de 30 kg/m^2 ou plus).

Vaccin contre la COVID-19 de Janssen

- Les données disponibles à ce jour des essais cliniques ont montré que le vaccin contre la COVID-19 de Janssen est efficace à 67 % contre le SRAS-CoV-2 symptomatique modéré à sévère/critique au moins deux semaines après avoir reçu une dose.
- L'efficacité potentielle était constante dans l'ensemble des groupes d'âge.
- Les estimations ponctuelles de l'efficacité potentielle du vaccin contre une infection par le SRAS-CoV-2 confirmée symptomatique modérée à sévère/critique 28 jours après la vaccination étaient comparables à celles de l'essai effectué au Brésil (68 %), où les deux tiers des isolats appartenaient au variant P.2 (zêta), et à celles de l'essai effectué en Afrique du Sud (64 %), où presque tous les isolats correspondaient au variant B.1.351 (béta).
- Les ÉI locaux et systémiques étaient typiquement légers et transitoires, et aucun signalement en matière d'innocuité n'a été détecté dans les essais cliniques.
- En date du 24 mai 2021, 32 cas de STT se sont révélés porteurs des anticorps anti-PF4 après l'administration d'environ 10,2 millions de doses du vaccin de Janssen aux É.-U.
- Le vaccin est semblablement sûr et efficace chez les personnes ayant une ou plusieurs comorbidités 14 jours après la vaccination, bien que l'efficacité potentielle soit sensiblement plus faible chez les participants ayant des comorbidités 28 jours après la vaccination.

Vaccins à ARNm contre la COVID-19 comparés aux vaccins à vecteur viral

Le CCNI a passé en revue la récente épidémiologie de la COVID-19 au Canada (y compris la circulation des variants), les caractéristiques des vaccins (dont l'efficacité potentielle, l'efficacité réelle, l'innocuité), les données probantes et les orientations internationales sur la TTIV, l'approvisionnement prévu en vaccins, l'évaluation de Santé Canada des vaccins contre la COVID-19, ainsi qu'une analyse complète des répercussions sur l'éthique, l'équité, la faisabilité et l'acceptabilité [5] de ses recommandations sur l'utilisation des vaccins contre la COVID-19 au Canada.

Le CCNI a conclu que les avantages des vaccins contre la COVID-19 à ARNm sûrs et hautement efficaces l'emportent sur les inconvénients possibles pour les populations admissibles. Par conséquent, le CCNI a fortement recommandé l'utilisation préférentielle des vaccins à ARNm contre la COVID-19 dans tous les groupes d'âge autorisés. Le CCNI met en garde qu'il existe une incertitude quant aux données probantes sur les avantages et les risques liés à l'utilisation des vaccins à vecteur viral contre la COVID-19 pour les populations admissibles au Canada en raison du risque d'un ÉI rare mais grave (thrombocytopénie thrombotique induite par le vaccin, TTIV); la disponibilité d'autres vaccins à ARNm sûrs et hautement efficaces; ainsi que certaines données

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probantes sur une protection moindre contre la transmission asymptomatique et les VP B.1.351 (béta) et B.1.617.2 (delta) avec le vaccin d'AstraZeneca. Par conséquent, le CCNI a fait une recommandation discrétionnaire sur l'utilisation de vaccins à vecteur viral contre la COVID-19.

Le CCNI avait auparavant fait une recommandation discrétionnaire sur l'utilisation de vaccins à vecteur viral contre la COVID-19 pour les personnes qui préfèrent un vaccin plus tôt que d'attendre un vaccin à ARNm, uniquement si certaines conditions étaient remplies (y compris une analyse avantages-risques, un consentement éclairé et un délai de réception important d'un vaccin à ARNm). Cette recommandation était fondée sur une analyse avantages-risques pour la santé publique utilisant les taux de TTIV signalés à ce moment-là (cette analyse est disponible dans les versions archivées de cette déclaration). Toutefois, avec l'augmentation des taux signalés de TTIV après l'administration des vaccins à vecteur viral et l'augmentation des approvisionnements en vaccins à ARNm au Canada, le CCNI recommande maintenant que les vaccins à vecteur viral ne soient offerts que si les vaccins à ARNm sont contre-indiqués ou inaccessibles.

Un sommaire des données probantes et justification pour la recommandation préférentielle du CCNI sur l'utilisation des vaccins à ARNm contre la COVID-19 dans le cadre de programmes destinés à la population et une recommandation discrétionnaire sur l'utilisation d'un vaccin à vecteur viral contre la COVID-19 pour les personnes lorsque d'autres vaccins contre la COVID-19 autorisés sont contre-indiqués ou inaccessibles figure ci-dessous :

- **Épidémiologie** : L'épidémiologie et le risque de contracter la COVID-19 varient à travers le Canada et entre les populations. La proportion des cas de COVID-19 classifiés comme des VP augmente au Canada. Les cas classifiés de VP sont hospitalisés plus souvent que ceux sans VP chez les 20 ans et plus. Le CCNI continuera à surveiller l'évolution de l'épidémiologie.
- **Efficacité potentielle et efficacité réelle** : Les données émergentes laissent croire que tous les vaccins autorisés offrent une protection contre les hospitalisations et vraisemblablement les décès attribuables à la COVID-19. Dans les essais cliniques, les vaccins à ARNm contre la COVID-19 ont montré une efficacité potentielle accrue par rapport aux vaccins à vecteur viral contre la COVID-19. Il existe des données probantes montrant que les vaccins à ARNm contre la COVID-19 et le vaccin contre la COVID-19 d'AstraZeneca protègent contre le VP B.1.1.7 (alpha). Il existe également des données probantes émergentes sur l'efficacité du vaccin qui suggèrent que le vaccin de Pfizer-BioNTech offre une très bonne protection (87,9 %) et le vaccin d'AstraZeneca offre une bonne protection (59,8 %) contre le VP B.1.617.2 (delta) après la deuxième dose. L'efficacité est beaucoup plus faible après une seule dose de vaccins de Pfizer-BioNTech et d'AstraZeneca (33,2 % et 32,9 %, respectivement). Les vaccins à ARNm contre la COVID-19 et le vaccin contre la COVID19 de Janssen semblent offrir une protection contre le VP B.1.351 (béta), mais le vaccin contre la COVID-19 d'AstraZeneca n'en offre pas. Dans les études menées au Brésil, on a montré que le vaccin de Janssen offre une protection contre le VI P.2 (zêta). Il y a des données probantes limitées sur la protection qu'offrent les vaccins à ARNm ou à vecteur viral contre la COVID-19 face au VP P.1 (gamma).
- **Innocuité** :
    - De très rares cas de caillots sanguins graves associés à une thrombocytopénie ont été signalés dans le monde après l'administration des vaccins à vecteur viral contre la COVID-19. Le taux de TTIV est estimé entre 1 pour 26 000 et 1 pour 100 000 personnes vaccinées avec une première dose du vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD. Au 1 juin 2021, l'ASPC a estimé le taux de TTIV au Canada à 1 sur 73 000 doses administrées. Toutefois, à mesure que les recherches se poursuivent, ce taux pourrait atteindre 1 sur 50 000. Le taux de

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létalité de la TTIV varie également d'un pays à l'autre et se situe entre 20 et 50 %. De nombreux cas ont été signalés comme ayant une morbidité grave à long terme, y compris des lésions neurologiques. Au 24 mai 2021, 32 cas de cet EI ont été confirmés après environ 10,2 millions de doses du vaccin de Janssen administrées aux É.-U., et d'autres sont en cours d'investigation.

- De très rares cas d'une maladie grave appelée syndrome de fuite capillaire (SFC) ont été signalés après l'administration du vaccin contre la COVID-19 d'AstraZeneca.
- La surveillance de l'innocuité post-commercialisation des vaccins à ARNm contre la COVID-19 a révélé une fréquence accrue de myocardite et de péricardite plus souvent après une deuxième dose d'un vaccin à ARNm contre la COVID-19 et chez les jeunes adultes et adolescents de sexe masculin. Toutefois, la majorité des cas signalés étaient bénins et les personnes avaient tendance à récupérer rapidement.

- **Éthique** : Le CCNI a consulté le Groupe consultatif en matière d'éthique en santé publique (GCESP) sur les considérations d'ordre éthique concernant la restriction de l'utilisation d'un vaccin à vecteur viral pendant la pandémie actuelle et prévue et dans le contexte d'approvisionnement en vaccins. Le GCESP a fourni des recommandations dans les domaines suivants : promotion du mieux-être et réduction du risque, maintien de la confiance, respect envers les personnes et encouragement à l'autonomie et promotion de la justice et de l'équité. Le CCNI a intégré ces recommandations à ses orientations. Le CCNI a appliqué le principe de précaution en formulant sa recommandation discrétionnaire et a tenu compte de l'évolution des données probantes sur la TTIV, le risque de préjudice, la disponibilité d'autres vaccins efficaces dont le signalement en matière d'innocuité est nul, et vu les données probantes sur l'efficacité d'autres mesures de prévention et de contrôle des infections.
- **Équité :** Le CCNI a examiné l'impact des diverses recommandations sur toutes les populations afin qu'elles puissent réaliser pleinement et équitablement leur potentiel de santé [5]. Les populations qui ont reçu un vaccin à vecteur viral contre la COVID-19 lorsque les approvisionnements en vaccins à ARNm étaient limités se sont prévalues d'une protection contre la COVID-19 plus tôt que si elles avaient attendu de se voir proposer des vaccins à ARNm disponibles. Toutefois, ces populations peuvent ultimement se prévaloir d'une protection moindre puisqu'une proportion accrue de la population vaccinée demeurera susceptible. Le CCNI a considéré l'impact de l'approvisionnement d'un vaccin moins efficace ayant un signalement préoccupant en matière d'innocuité dans des populations marginalisées et désavantagées qui ont été touchées de manière disproportionnelle par la pandémie dont l'expérience de vie a mené à la méfiance des gouvernements. Selon les stratégies de vaccination, les inégalités en matière de santé pourraient être exacerbées si ce préjudice potentiel n'est pas pris en compte lors de la mise en œuvre du programme de vaccination auprès des populations qui présentent des facteurs de risque croisés de maladie sévère et d'exposition (p. ex., les populations racialisées vivant dans des logements multigénérationnels avec une surreprésentation dans les emplois fournissant des services essentiels tels que l'alimentation et les soins de santé). Avec l'augmentation de l'offre de vaccins à ARNm, les inégalités seront réduites si les vaccins à vecteur viral ne sont proposés que lorsque les vaccins à ARNm sont contre-indiqués ou inaccessibles.
- **Faisabilité** : Le CCNI a considéré l'impact de ses recommandations sur la mise en œuvre réussie des programmes de vaccination contre la COVID-19 dans un contexte local ayant des ressources disponibles [5]. Le Canada s'est procuré et s'attend à recevoir assez de vaccins à ARNm pour assurer l'immunisation de la population canadienne admissible par

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une série complète avant l'automne 2021, et un approvisionnement suffisant pour permettre à tous les Canadiens admissibles de recevoir leur première dose d'ici juin 2021. Les fournitures prévues des vaccins à vecteur viral contre la COVID-19 pour le Canada sont minimales par rapport aux fournitures prévues des vaccins ARNm. Ainsi, le délai anticipé pour se voir proposer un vaccin à ARNm est maintenant réduit mais il pourrait varier entre les populations et à travers les administrations. L'utilisation du vaccin de Janssen est autorisée en dose unique. Toutefois, sa durée de protection contre la COVID-19 est inconnue.

- **Acceptabilité** : Le CCNI a révisé les données récentes du Canada pour considérer l'impact potentiel de ses recommandations sur l'intention et les comportements concernant la vaccination contre la COVID-19 [2]. La volonté de se faire vacciner continue à augmenter. Toutefois, diverses populations qui ont été touchées de manière disproportionnelle par la pandémie hésitent davantage ou vivent des obstacles relatifs à l'administration d'un vaccin contre la COVID-19 (p. ex., populations racialisées, migrants ou travailleurs sans papiers). Tandis qu'un sondage sur l'opinion publique mené en mars 2021 a suggéré que 44-60 % des Canadiens n'avaient aucune préférence quant au vaccin qu'ils allaient recevoir, des enquêtes réalisées au début du mois d'avril 2021 ont révélé que les Canadiens qui ont l'intention de se faire vacciner sont beaucoup plus à l'aise avec les vaccins à ARNm (90-92 %) qu'avec les vaccins de Janssen (70 %) ou d'AstraZeneca (41 %) [113]. Un sondage de suivi mené à la fin du mois d'avril 2021 a révélé que si le confort avec les vaccins à ARNm restait élevé (90-92 %), le confort de recevoir le vaccin de Janssen a diminué à 54 % et était similaire au confort de recevoir le vaccin d'AstraZeneca (52 %) [114]. Un sondage auprès de Canadiens mené au début du mois de mai 2021 a révélé que parmi les répondants non vaccinés, 65 % ont indiqué qu'ils avaient une préférence pour le vaccin, la plupart étant disposés à recevoir des vaccins à ARNm (58-82 %) par rapport aux vaccins à vecteur viral (7-16 %) [115]. Des données recueillies au cours de la pandémie ont révélé de façon constante que les Canadiens indiquent « qu'assurer l'innocuité du vaccin » comme la raison principale de retarder ou de refuser la vaccination contre la COVID-19. Le CCNI a résumé de manière transparente les meilleures données probantes disponibles (connues et inconnues) pour élaborer des orientations d'experts éclairées et accroître la confiance en ses recommandations.

3. **Le CCNI recommande que les autorités compétentes maximisent le nombre de personnes recevant la première dose d'un vaccin contre la COVID-19 en prolongeant la deuxième dose de vaccin contre la COVID-19 *jusqu'à quatre mois* après la première dose. Avec l'expansion de l'approvisionnement en vaccins contre la COVID-19 au Canada, la deuxième dose devrait être offerte dès que possible après ou en même temps que la première dose pour toutes les populations admissibles restantes, la priorité étant donnée aux personnes présentant le plus grand risque de maladie sévère et de décès attribuable à la COVID-19. *(Forte recommandation du CCNI)***

Sommaire des données probantes et justification :

- La morbidité et la mortalité attribuables à la COVID-19 persistent toujours. La prolongation de l'intervalle jusqu'à la deuxième dose permet de vacciner le plus grand nombre de personnes le plus rapidement possible, ce qui assure un plus grand nombre de personnes une protection plus directe et la possibilité d'une protection indirecte et collective.
- Un intervalle prolongé allant jusqu'à quatre mois permet de proposer au plus grand nombre possible de populations éligibles la vaccination avec une dose. L'intervalle entre la première et la deuxième dose peut être raccourci selon l'approvisionnement accru en vaccins et ne

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devrait pas être prolongé plus longtemps que nécessaire pour offrir les premières doses de vaccin aux personnes admissibles.

- Les données probantes actuelles indiquent une très bonne efficacité potentielle contre la COVID-19 symptomatique avec une dose d'un vaccin contre la COVID-19 : bonne efficacité réelle indiquée selon des études d'observation (généralement entre 60 et 80 %, avec quelques estimations inférieures et supérieures) contre la maladie symptomatique et/ou l'infection asymptomatique; ainsi qu'une très bonne efficacité réelle contre l'hospitalisation (environ 80 %) et le décès (85 % selon une étude en provenance du R.-U. Alors que deux doses de vaccins à ARNm ont révélé un excellent niveau d'efficacité (potentielle et réelle), une dose de ce type de vaccin semble offrir un rendement semblable à une ou deux doses du vaccin d'AstraZeneca. Toutefois, des données probantes émergentes suggèrent une protection réduite offerte par une dose des vaccins de Pfizer-BioNTech et d'AstraZeneca contre le VP B.1.617.2 (delta).
- L'efficacité réelle a été démontrée jusqu'à deux mois après la première dose des vaccins à ARNm, et la publication de l'essai clinique d'AstraZeneca a modélisé l'efficacité potentielle à une dose jusqu'à 90 jours après la vaccination.
- Des avis d'experts éclairés fondés sur les principes de l'immunologie indiquent qu'un intervalle plus long entre les doses d'amorçage et de rappel d'une série de vaccins entraîne une réponse meilleure et plus durable. L'essai clinique du vaccin d'AstraZeneca contre la COVID-19 a démontré une efficacité potentielle optimale lorsque l'intervalle entre la première et la deuxième dose était supérieur ou égal à 12 semaines.
- L'efficacité de la stratégie de doses prolongées sera surveillée sur une base continue. Si cela est indiqué, les recommandations seront révisées.

Cette recommandation s'applique à tous les vaccins contre la COVID-19 à deux doses disponibles dont l'utilisation est actuellement autorisée au Canada.

Veuillez consulter la déclaration du CCNI sur l'allongement des intervalles entre les doses des vaccins contre la COVID-19 pour optimiser les campagnes de vaccination précoces et la protection des populations au Canada (archivée) dans le contexte d'un approvisionnement limité en vaccins, pour un résumé des données probantes et une justification supplémentaire de cette recommandation.

4. Le CCNI recommande de proposer une série complète de vaccin contre la COVID-19 aux personnes appartenant au groupe d'âge autorisé qui ne présentent pas de contre-indications au vaccin et qui ont déjà eu une infection par le SRAS-CoV-2 confirmée par PCR. *(Recommandation discrétionnaire du CCNI)*

Sommaire des données probantes et justification :

- Il n'est pas nécessaire de procéder à un test de dépistage d'une infection antérieure au SRAS-CoV-2 avant la vaccination contre la COVID-19.
- Le 30 mars, le CCNI a réaffirmé sa recommandation selon laquelle les personnes antérieurement infectées par le SRAS-CoV-2 se voient proposer une série complète d'un vaccin contre la COVID-19 après la prise en compte de données probantes tirées d'études observationnelles concernant l'immunogénicité et l'innocuité de la vaccination chez les personnes antérieurement infectées, les données sur l'innocuité provenant d'essais cliniques clés de l'utilisation des vaccins approuvés au Canada, ainsi que les présentations du Réseau national canadien pour l'innocuité des vaccins (CANVAS) et l'étude RECOVER de l'Université de Montréal.

CONFIDENTIEL

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- En l'absence de données sur l'efficacité réelle d'un vaccin à une dose chez les personnes antérieurement infectées (notamment dans le cas des VP), de données limitées sur l'innocuité d'un vaccin à deux doses (p. ex., l'impact de la gravité de la maladie et de l'intervalle depuis la dernière infection, sur la réactogénicité), et des défis programmatiques potentiels associés à la communication et à la mise en œuvre d'une stratégie à une dose, les personnes antérieurement infectées par le SRAS-CoV-2 devraient continuer à recevoir une série complète d'un vaccin aux intervalles recommandés, peu importe la gravité de l'infection précédente.
- À l'heure actuelle, on manque de données probantes sur les différences potentielles d'efficacité des vaccins entre les individus qui manifestent des signes d'infection antérieure par le SRAS-CoV-2 et ceux qui n'en manifestent pas. Dans le cadre des essais cliniques portant sur les vaccins contre la COVID-19 réalisés à ce jour, les personnes atteintes d'une infection par le SRAS-CoV-2 confirmée par PCR ont été exclues, et seul un petit nombre de participants aux essais présentant des signes sérologiques d'infection antérieure (IgG+) étaient atteints d'une COVID-19 symptomatique confirmée; l'efficacité potentielle dans cette population est donc incertaine.
- À l'heure actuelle, il y a des données limitées sur les différences potentielles de réactogénicité entre les personnes qui ont manifesté des signes d'infection antérieure par le SRAS-CoV-2 et celles qui n'en ont pas manifesté. Il n'existe pas de données probantes suffisantes sur l'impact de la gravité de l'infection antérieure et sur l'impact de l'intervalle entre une infection antérieure et le moment de l'administration de la première dose sur la réactogénicité.
- La réponse immunitaire au SRAS-CoV-2 et au VP, y compris la durée de l'immunité et de la protection croisée, n'est pas encore bien comprise. Des réinfections par le SRAS-CoV-2 et des variants ont été signalées, et des recherches sont en cours pour établir la gravité, la fréquence et les facteurs de risque de telles réinfections. Il y a des données limitées suggérant que les personnes ayant été antérieurement infectées peuvent générer une réponse comparable ou accrue à une seule dose d'un vaccin par rapport aux personnes n'ayant pas contracté le SRAS-CoV-2 qui ont reçu deux doses.
- Dans le contexte d'un approvisionnement limité, pour permettre la protection du plus grand nombre d'individus à risque possible, la vaccination par un vaccin contre la COVID-19 peut être retardée de 3 mois après une infection confirmée par PCR, car les réinfections déclarées à ce jour ont été rares pendant les trois premiers mois suivant l'infection. Toutefois, si cela se révèle difficile du point de vue de la faisabilité, les administrations peuvent choisir de ne pas tenir compte du statut d'infection antérieure par le SRAS-CoV-2 ainsi confirmées et vacciner tous les membres d'une population clé donnée.
- Par mesure de précaution et compte tenu de la nécessité de pouvoir surveiller les ÉI des vaccins contre la COVID-19 sans risque de confusion avec les symptômes de la COVID-19 ou d'autres maladies coexistantes, et pour réduire au minimum le risque de transmission de la COVID-19 sur un lieu de vaccination, le CCNI recommande que les symptômes d'une maladie aiguë aient complètement disparu avant d'administrer un vaccin contre la COVID-19, et de s'assurer que l'individu n'est plus considéré comme étant infectieux selon les critères actuels.
- Le CCNI continuera de surveiller les données probantes concernant la vaccination chez les personnes précédemment infectées pas le SRAS-COV-2 et mettra à jour les recommandations si nécessaire.

Les populations suivantes ont été exclues des essais cliniques ou représentées par un moindre nombre de participants aux essais cliniques pivots originaux. Le CCNI a mis à jour des recommandations pour ces populations à mesure que des données probantes en

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conditions réelles (surtout avec la vaccination à ARNm) sont devenues disponibles. Dès maintenant, les recommandations citées plus haut sur l'utilisation des vaccins à ARNm contre la COVID-19 (Recommandation n° 1) et sur l'utilisation des vaccins à vecteur viral contre la COVID-19 (Recommandation n° 2), s'appliquent également aux personnes qui sont immunodéprimées, qui souffrent d'une maladie auto-immune, qui sont enceintes ou qui allaitent. Des précisions sur le consentement éclairé dans ces recommandations et un résumé des données probantes et de la justification des recommandations dans ces populations sont inclus ci-dessous.

Personnes immunodéprimées

5. **Le CCNI recommande de préférence de proposer une série complète de vaccins à ARNm contre la COVID-19 aux personnes appartenant au groupe d'âge autorisé qui sont immunodéprimées en raison d'une maladie ou d'un traitement. Le consentement éclairé devrait inclure une discussion sur la possibilité que des personnes immunodéprimées puissent présenter une réponse immunitaire réduite à l'un ou l'autre des vaccins autorisés contre la COVID-19.** ***(Forte recommandation du CCNI)***

6. **Le CCNI recommande qu'un vaccin à vecteur viral contre la COVID-19 soit proposé aux personnes appartenant au groupe d'âge autorisé qui sont immunodéprimées en raison d'une maladie ou d'un traitement pour initier une série lorsque d'autres vaccins contre la COVID-19 autorisés sont contre-indiqués ou inaccessibles. Le consentement éclairé devrait inclure une discussion sur les risques et les symptômes de la TTIV, la nécessité de consulter immédiatement un médecin en cas d'apparition de symptômes, ainsi que les données probantes limitées sur l'utilisation des vaccins à vecteur viral contre la COVID-19 dans cette population.** ***(Recommandation discrétionnaire du CCNI)***

Sommaire des données probantes et justification :

- Les participants aux essais cliniques sur le vaccin contre la COVID-19 comprenaient uniquement des personnes qui n'étaient pas immunodéprimées, comme des participants atteints d'une infection stable au virus de l'immunodéficience humaine (VIH), et ceux qui ne recevant pas de traitement immunosuppresseur pendant l'essai. Toutefois, des données probantes en conditions réelles (principalement pour la vaccination à ARNm) sont devenues disponibles.
- L'efficacité potentielle des vaccins contre la COVID-19 chez les personnes immunodéprimées est actuellement inconnue. **Les personnes devraient continuer à suivre les mesures de santé publique recommandées pour la prévention et le contrôle de l'infection et de la transmission du SRAS-CoV-2.** Les personnes immunodéprimées, y compris les personnes recevant un traitement immunosuppresseur, peuvent avoir une réponse immunitaire diminuée au vaccin. **Une série de vaccins devrait être idéalement complétée au moins deux semaines avant le début des traitements immunosuppresseurs si possible.**
- Aucun signalement en matière d'innocuité n'a été relevé à ce jour chez les participants non immunodéprimés présentant une maladie immunosuppressive (p. ex., une infection stable au VIH) inclus dans les essais cliniques.
- Les données sur l'innocuité chez les personnes immunodéprimées, y compris celles qui reçoivent un traitement immunosuppresseur, étaient disponibles à partir d'études observationnelles chez les receveurs de greffe d'organe solide, les patients atteints du cancer et les personnes atteintes de maladies inflammatoires chroniques

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(53)(54)(55)(56)(57)(58)(59)(60)(61)(62)(63)(64)(65)(66). La fréquence et la sévérité des ÉI après l'administration d'un vaccin à ARNm contre la COVID-19 dans ces populations étaient comparables à celles des personnes non-immunodéprimées dans le cadre de ces études et à ce qui avait été indiqué dans les essais cliniques. Les données sur l'innocuité dans ces populations après l'administration d'un vaccin à vecteur viral ne sont pas disponibles.

- Des études observationnelles chez les receveurs de greffe d'organe solide, les patients atteints du cancer et les personnes atteintes de maladies inflammatoires chroniques qui recevaient un traitement immunosuppresseur ont montré des réponses immunitaires diminuées et retardées aux vaccins à ARNm contre la COVID-19 ou au vaccin contre la COVID-19 d'AstraZeneca (67)(68)(69)(59) (60)(61)(70)(71)(72)(73)(74)(64)(75)(66)(76)(77)(78)(79)(80)(55)(81)(57)(82)(58). Il y a des données probantes limitées pour affirmer que les réponses immunitaires s'améliorent après une deuxième dose du vaccin et que le degré d'amélioration varie selon le type de traitement immunosuppresseur ou d'affection (58) (77)(74)(71)(80)(73)(61)(79). Vu le nombre limité de participants et le manque de corrélat de protection immunologique contre l'infection par le SRAS-CoV-2, il y a des limites à interpréter l'importance de ces études observationnelles.
- En général, les vaccins non-vivants peuvent être administrés aux personnes immunodéprimées. Toutefois, la portée et la durée de l'immunité acquise par une vaccination sont souvent réduites. On ignore actuellement si les personnes immunodéprimées seront capables de développer une réponse immunitaire aux vaccins autorisés contre la COVID-19.
- Les personnes vivant avec le VIH qui sont considérées comme étant immunodéprimées devraient être vaccinées. Dans des études observationnelles et des essais cliniques, les réponses immunitaires humorales et cellulaires étaient semblables entre les personnes entièrement vaccinées vivant avec le VIH et celles qui étaient séronégatives (116)(117)(118).
- Le degré relatif d'immunodéficience chez les personnes immunodéprimées varie selon l'affection sous-jacente, la progression de la maladie et l'utilisation de médicaments qui suppriment la fonction immunitaire.
- Actuellement, il y a des données probantes limitées qui indiquent que l'immunodéficience ou l'immunosuppression est un facteur de risque indépendant lié à la COVID-19 sévère, bien que les données probantes évoluent. Une revue rapide des données probantes provenant d'études menées dans des pays membres de l'OCDE a révélé des données probantes de certitude modérée sur l'association faible ou nulle avec les décès attribuables à la COVID-19 chez les personnes ayant une immunosuppression non spécifiée et sur l'augmentation faible ou nulle des hospitalisations attribuables à la COVID-19 avec malignité (4). La revue a trouvé des données probantes de faible certitude sur l'augmentation d'au moins le double des décès attribuables à la COVID-19 chez les personnes ayant une drépanocytose ou une immunodéficience sévère; un cancer métastatique (chez les moins de 70 ans); de la chimiothérapie au cours des douze derniers mois ou de la radiothérapie au cours des six derniers mois; une greffe d'organe solide, de moelle osseuse ou de cellules souches. Il faut faire preuve de prudence en matière d'interprétation des données probantes de faible certitude. Il y avait également des données probantes de faible certitude sur l'augmentation d'au moins le double des hospitalisations attribuables à la COVID-19 pour les greffes de tout type. Toutefois, la revue a révélé des données probantes de certitude modérée sur une augmentation d'au moins le double des hospitalisation et des décès si une personne souffrait d'au moins deux affections médicales sous-jacentes, comparativement aux personnes sans comorbidités. Aucune donnée probante directe sur la combinaison d'affections médicales associées à un risque accru n'a été trouvée (7)(9).
- Les données de surveillance canadiennes récentes indiquent que par rapport à la population générale, une proportion plus élevée de la population immunodéprimée ou celle atteinte de malignité est hospitalisée ou admise à l'USI en raison de la COVID-19.

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- Il est fortement encouragé d'exercer une surveillance active de ces sujets vaccinés. Le CCNI suivra l'évolution des données probantes et mettra à jour ses recommandations si nécessaire.

Pour consulter les définitions et pour de plus amples renseignements généraux, voir la Section Immunisation des sujets immunodéprimés du GCI, Partie 3 – Vaccination de populations particulières.

Personnes atteintes d'une maladie auto-immune

7. **Le CCNI recommande de préférence de proposer une série complète de vaccins à ARNm contre la COVID-19 aux personnes appartenant au groupe d'âge autorisé qui sont atteintes d'une maladie auto-immune. Le consentement éclairé devrait inclure une discussion sur les données probantes émergentes concernant l'innocuité des vaccins à ARNm contre la COVID-19 dans ces populations.** ***(Forte recommandation du CCNI)***

8. **Le CCNI recommande qu'un vaccin à vecteur viral contre la COVID-19 soit proposé aux personnes appartenant au groupe d'âge autorisé présentant une maladie auto-immune pour initier une série lorsque d'autres vaccins contre la COVID-19 autorisés sont contre-indiqués ou inaccessibles. Le consentement éclairé devrait inclure une discussion sur les risques et les symptômes de la TTIV, la nécessité de consulter immédiatement un médecin en cas d'apparition de symptômes, ainsi que les données probantes limitées sur l'utilisation des vaccins à vecteur viral contre la COVID-19 dans cette population.** ***(Recommandation discrétionnaire du CCNI)***

Sommaire des données probantes et justification :

- Bien que les participants atteints de maladies auto-immunes qui n'étaient pas immunodéprimés n'aient pas été exclus des essais, ils constituent une très faible proportion des participants aux essais et représentent un éventail très étroit de maladies auto-immunes. Toutefois, des données probantes en conditions réelles (principalement pour la vaccination à ARNm) sont devenues disponibles.
- D'autres applications des technologies de l'ARNm ont été pour le traitement du cancer, ce qui nécessitait une réponse immunitaire dirigée contre les cellules cancéreuses d'un individu. Cela a soulevé une préoccupation théorique selon laquelle les vaccins à ARNm contre les maladies infectieuses agiraient de façon semblable, provoquant de l'inflammation et potentiellement exacerbant une maladie auto-immune existante. Les applications actuelles de la technologie de l'ARNm pour les vaccins contre la COVID-19 ont été optimisées afin de réduire le risque; toutefois, une évaluation plus approfondie est nécessaire. La préoccupation théorique est semblable pour les vaccins à vecteur viral. Toutefois, les données probantes sur l'innocuité de la vaccination contre la COVID-19 chez les personnes atteintes d'une maladie auto-immune évoluent.
- Les études observationnelles chez les personnes ayant une maladie auto-immune indiquent que la fréquence et la sévérité des ÉI dans cette population sont comparables à celles des personnes qui ne souffrent pas de maladie auto-immune et à ce qui a été reporté dans les essais cliniques[53][54][55] [56][57][58][94]. L'apparition d'une nouvelle maladie auto-immune ou l'exacerbation de la maladie après l'administration des vaccins à ARNm contre la COVID-19 était rare ou comparable à l'incidence de fond de ces évènements dans la population générale. Des données sur l'innocuité au sein de ces populations après l'administration d'un vaccin à vecteur viral ne sont pas disponibles.

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- Les études observationnelles chez les personnes ayant une maladie de maladie auto-immunes qui prenaient des traitements immonosuppresseurs ont révélé des réponses immunitaires diminuées ou retardées aux vaccins ARNm ou AstraZeneca. Étant donné le nombre limité de participants et l'absence d'un corrélat immunologique de la protection contre l'infection par le SRAS-CoV-2, l'interprétation de la signification de ces études d'observation est limitée [80][55][81][57][82][58].
- Le spectre des maladies auto-immunes est varié. Le degré relatif d'auto-immunité chez les personnes atteintes de maladies auto-immunes varie selon l'affection sous-jacente, la progression de la maladie et l'utilisation de médicaments qui ont un impact sur la fonction immunitaire.
- Les données probantes sur les maladies auto-immunes en tant que facteur de risque indépendant lié à la COVID-19 sévère évoluent. Une revue rapide des données probantes provenant d'études menées dans des pays membres de l'OCDE a trouvé de solides données probantes (de certitude modérée) sur l'augmentation d'au moins le double des décès attribuables à la COVID-19 pour les cas de diabète de type 1, ainsi qu'avec un groupe de troubles neurologiques, y compris la sclérose en plaques et la myasthénie grave. La revue a également révélé des données probantes de faible certitude sur une forte augmentation des hospitalisations liées aux cas de vascularite [7]. La revue a trouvé des données probantes de certitude modérée sur une association faible ou nulle avec des décès ou des hospitalisations attribuables à la COVID-19 pour les cas de polyarthrite rhumatoïde, de maladie rhumatismale ou du tissu conjonctif ou de lupus érythémateux disséminé [7]. Il faut faire preuve de prudence en matière d'interprétation des données probantes de faible certitude. Toutefois, la revue a révélé des données probantes à certitude modérée sur une augmentation d'au moins le double des hospitalisation et des décès si une personne souffrait d'au moins deux affections médicales sous-jacentes, comparativement aux personnes sans comorbidités. Aucune donnée probante directe sur la combinaison d'affections médicales associées à un risque accru n'a été trouvée [7][9].
- Il est fortement encouragé d'exercer une surveillance active de ces sujets vaccinés. Le CCNI suivra l'évolution des données probantes et mettra à jour ses recommandations si nécessaire.

Pour plus d'informations générales sur les maladies auto-immunes, voir la Section Immunisation des personnes atteintes de maladies chroniques du GIC, Partie 3 – Vaccination de populations particulières.

Grossesse et allaitement

9. Le CCNI recommande de préférence de proposer une série complète de vaccins à ARNm contre la COVID-19 aux personnes enceintes ou allaitantes appartenant au groupe d'âge autorisé. Le consentement éclairé devrait inclure une discussion sur les données probantes émergentes concernant l'innocuité des vaccins à ARNm contre la COVID-19 dans ces populations. *(Forte recommandation du CCNI)*

10. Le CCNI recommande qu'un vaccin à vecteur viral contre la COVID-19 soit proposé aux personnes enceintes ou allaitantes appartenant au groupe d'âge autorisé pour initier une série lorsque d'autres vaccins contre la COVID-19 autorisés sont contre-indiqués ou inaccessibles. Le consentement éclairé devrait inclure une discussion sur les risques et les symptômes de la TTIV, la nécessité de consulter immédiatement un médecin en cas d'apparition de symptômes, ainsi que les données probantes limitées sur l'utilisation des

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vaccins à vecteur viral contre la COVID-19 dans ces populations. ***(Recommandation discrétionnaire du CCNI)***

Sommaire des données probantes et justification :

- Les personnes enceintes ou allaitantes ont été exclues des essais cliniques des vaccins à ARNm et à vecteur viral contre la COVID-19. Toutefois, les résultats chez les participantes qui sont tombées enceintes pendant les essais cliniques et les résultats chez le fœtus sont déclarés dans des registres, et des données probantes en conditions réelles (principalement pour la vaccination à ARNm) sont devenues disponibles.
- Un vaccin à ARNm est privilégié selon des données publiées sur l'innocuité. Des analyses préliminaires récemment publiées auprès de 35 691 personnes enceintes aux É.-U. qui ont reçu un vaccin à ARNm contre la COVID-19 n'a pas indiqué de signalement évident en matière d'innocuité [99]. Si la TTIV devait survenir après l'administration d'un vaccin à vecteur viral chez une personne enceinte, il pourrait y avoir des complexités dans les soins médicaux. Des données sur l'innocuité aux É.-U. suggèrent que l'administration d'un vaccin à ARNm dans les 30 jours suivant la conception est sûre [99]. Les personnes qui tentent de devenir enceintes n'ont pas besoin d'éviter la grossesse après l'administration d'un vaccin à ARNm.
- Une analyse des données recueillies à partir des registres de vaccination contre la COVID-19 à l'échelle internationale à ce jour n'a pas révélé de signalement en matière d'innocuité maternelle ou néonatale.
  À ce jour, aucun signalement en matière d'innocuité n'a été détecté dans le cadre des études animales DART pour les vaccins de Pfizer [96], de Moderna [95], de Janssen [119] et d'AstraZeneca [98].
- Les données probantes émergentes suggèrent que la vaccination à ARNm contre la COVID-19 pendant la grossesse donne lieu à des titres d'anticorps comparables à ceux des personnes qui ne sont pas enceintes [101] [102] [103]. La réponse humorale IgG maternelle aux vaccins à ARN contre la COVID-19 passe du placenta au fœtus, entraînant ainsi un titre d'anticorps important et potentiellement protecteur à la circulation sanguine néonatale une semaine suivant la deuxième dose [104] [101] [105] [106].
- Les études observationnelles montrent systématiquement que les anti-S IgG et IgA sont présents dans le lait maternel au moins 6 semaines après l'administration des vaccins à ARNm [107][108][109][110][120][121][100][122].
- Dans une petite étude de cohorte, l'ARNm des vaccins contre la COVID-19 étaient indétectables dans le lait maternel 4-48 heures après la vaccination. Aucun signalement en matière d'innocuité n'a été détecté pour la vaccination à ARNm pendant l'allaitement, et les personnes en question devraient poursuivre l'allaitement après la vaccination [100].
- Les données probantes sur la grossesse comme facteur de risque indépendant lié à la COVID-19 sévère évoluent. Une revue rapide des données probantes provenant d'études menées dans des pays membres de l'OCDE a trouvé des données probantes de faible certitude sur l'augmentation d'au moins le double des hospitalisations attribuables à la COVID-19 pour les cas de grossesse (de tout stade) et des données probantes de faible certitude sur l'augmentation faible à nulle des décès. Il faut faire preuve de prudence en matière d'interprétation des données probantes de faible certitude. Toutefois, la revue a révélé des données probantes de certitude modérée sur l'augmentation d'au moins le double des hospitalisation et des décès si une personne souffrait d'au moins deux affections médicales sous-jacentes, comparativement aux personnes sans comorbidités. Aucune donnée probante directe sur la combinaison d'affections médicales associées à un risque accru n'a été trouvée [7][9].

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- Comparativement aux personnes qui ne sont pas enceintes, l'infection par le SRAS-CoV-2 pendant la grossesse peut augmenter le risque des complications nécessitant des hospitalisations et des soins intensifs, la naissance prématurée et les accouchements par césarienne. Une revue de 438 548 personnes enceintes ont trouvé que la grossesse est un facteur de risque pour les issues de grossesse moins favorables, comme la prééclampsie, la naissance prématurée et la mortinaissance, et que ces risques sont beaucoup plus élevés en cas d'infection sévère [123]. Une surveillance canadienne de la COVID-19 pendant la grossesse représentant cinq provinces du 1 mars au 21 décembre 2020 avec un échantillon de 1 880 cas positifs enceintes a remarqué un risque accru d'être hospitalisé (RR = 5.33, 95 % CI : 4.51 à 6.20 %) et un risque accru d'être admis à l'USI (RR=5.88, 95% CI: 3.80 à 8.22 %) par rapport aux homologues non enceintes [124]. Un support de ventilation pendant la grossesse est beaucoup plus difficile et les risques sont plus élevés chez la mère et l'enfant.
- Les sujets vaccinés et les fournisseurs de soins de santé sont encouragés à déclarer toute exposition au vaccin contre la COVID-19 pendant la grossesse dans les registres des personnes enceintes ayant reçu un vaccin contre la COVID-19 (voir l'Annexe F pour consulter une liste des registres de personnes enceintes ayant reçu un vaccin contre la COVID-19). La déclaration opportune des ESSI à l'autorité locale de santé publique, ainsi qu'au fabricant du vaccin, aux fins de suivi de ces sujets vaccinés est fortement encouragée.
- Le CCNI encourage la recherche accrue sur la vaccination contre la COVID-19 pendant la grossesse et l'allaitement.
- Le CCNI suivra l'évolution des données probantes et mettra à jour ses recommandations si nécessaire.

Pour de plus amples renseignements généraux, voir la Section Immunisation durant la grossesse et l'allaitement du GCI, Partie 3 – Vaccination de populations particulières.

Enfants et adolescents

11. Le CCNI recommande qu'une série complète du vaccin contre la COVID-19 de Pfizer-BioNTech soit proposée aux personnes de 12 à 15 ans sans contre-indications au vaccin. Le consentement éclairé devrait inclure une discussion sur les cas très rares de myocardite et/ou de péricardite dans la semaine suivant l'administration d'une dose d'un vaccin à ARNm. *(Forte recommandation du CCNI)*

À l'échelle internationale, des cas de myocardite et/ou de péricardite suivant la vaccination à ARNm ont été signalés le plus souvent chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose.

Voir la recommandation du CCNI sur l'utilisation du vaccin contre la COVID-19 de Pfizer-BioNTech chez les adolescents de 12 à 18 ans.

Sommaire des données probantes et justification :

- Les adolescents de 12 à 15 ans et moins représentent 4 % de la population canadienne et constituent moins de 4 % des cas de COVID-19 signalés au Canada jusqu'au 8 juin 2021. Les adolescents représentent moins de 0,5 % des hospitalisations associées à la COVID-19, moins de 0,5 % des cas de COVID-19 admis à l'USI et moins de 0,01 % des décès attribuables à la COVID-19.
- Toutefois, il y a des rapports récents d'épidémies de COVID-19 affectant des enfants, spécifiquement liées au variant B.1.617.2 (delta), dans des zones où les taux de vaccination sont relativement élevés dans la population adulte. Des preuves probantes indiquant si des

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VP spécifiques du SRAS-CoV-2, tels que le variant B.1.617.2 (delta), peuvent être plus infectieux en raison d'une transmissibilité accrue ou d'une protection indirecte réduite conférée par la vaccination à ARNm des adultes sont encore en émergence.

- Au Canada, la majorité des personnes de 17 ans et moins hospitalisées ou admises à l'USI en raison de la COVID-19 souffraient d'au moins une affection de santé sous-jacente, le plus souvent l'asthme, la maladie d'immunodéficience et le cancer [125].
- Des données probantes tirées d'un essai clinique pivot du vaccin contre la COVID-19 de Pfizer-BioNTech chez les adolescents de 12 à 15 ans ont montré un profil d'innocuité, d'immunogénicité et d'efficacité potentielle semblable à celui qui avait été signalé chez les personnes de 16 à 25 ans et plus [126].
- La surveillance de l'innocuité post-commercialisation des vaccins à ARNm contre la COVID-19 a révélé une fréquence accrue de myocardite et de péricardite, le plus souvent chez les adolescents et les jeunes adultes de 30 ans et moins, plus souvent chez les hommes que chez les femmes et plus souvent après la deuxième dose. Toutefois, la majorité des cas ont été bénins et se sont résolus.

Voir *Le consentement éclairé pour les vaccins à ARNm contre la COVID-19 devrait inclure des renseignements sur les très rares cas de myocardite ou de péricardite dans la semaine suivant un vaccin à ARNm* pour de plus amples directives.

- Il est fortement encouragé d'exercer une surveillance active chez les adolescents vaccinés. Le CCNI suivra l'évolution des données probantes et mettra à jour ses recommandations si nécessaire.
- Des données probantes sur la vaccination contre la COVID-19 chez les personnes de moins de 12 ans ne sont pas disponibles pour le moment. Le CCNI surveille les données probantes et mettra à jour ses recommandations lorsque les résultats deviendront disponibles.

Le CCNI continue à recommander ce qui suit :

- Les programmes de vaccination systématique et la vaccination avec d'autres vaccins recommandés par le CCNI devraient se poursuivre pendant la pandémie de COVID-19 avec une atténuation des risques de transmission de COVID-19 pendant le processus de vaccination, comme indiqué dans les Lignes directrices provisoires sur la continuité des programmes d'immunisation pendant la pandémie de COVID-19.

- Il faudrait continuer à encourager la poursuite des essais cliniques évaluant les vaccins contre la COVID-19 afin d'inclure des personnes potentiellement vulnérables à des maladies liées à des facteurs biologiques (p. ex., affections préexistantes, fragilité, grossesse et allaitement, immunodéficience) et sociaux (p. ex., résidence dans des établissements de soins de longue durée ou dans des lieux surpeuplés/éloignés, appartenance à une population racialisée, profession), afin de s'assurer que les options en matière de vaccins sont corroborées par de solides données sur l'innocuité, l'immunogénicité et l'efficacité potentielle, comme le recommande le CCNI dans ses Priorités de recherche pour les vaccins contre la COVID-19 à l'appui des décisions de santé publique.

- En plus des activités de pharmacovigilance des vaccins qui sont en cours au Canada avec les essais cliniques de Phase 4 et les études post-commercialisation, il est recommandé de mener des recherches supplémentaires et de surveiller la vaccination contre la COVID-19, en particulier parmi les populations qui ne sont pas actuellement incluses dans les essais cliniques (p. ex., les personnes enceintes, les personnes allaitantes, les personnes

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immunodéprimées, les personnes âgées vivant dans des établissements de soins collectifs, les enfants et les adolescents). De plus, le CCNI recommande la poursuite des essais cliniques et le suivi continu des participants aussi longtemps que cela est possible sur le plan éthique, afin de déterminer le niveau d'immunité nécessaire pour prévenir la maladie et d'établir la durée de la protection, l'efficacité potentielle dans différentes sous-populations et l'innocuité à moyen et long terme.

Le CCNI continue à recommander les éléments suivants pour guider la prise de décision éthique, comme indiqué dans son document Orientations préliminaires sur les principales populations à immuniser en priorité contre la COVID-19 :

- Des efforts devraient être fournis pour améliorer l'accès aux services de vaccination afin de réduire les iniquités en matière de santé sans aggraver la stigmatisation ou la discrimination, et pour faire participer les populations marginalisées par le système et les populations racialisées à la planification des programmes d'immunisation.

- Les administrations devraient assurer une surveillance étroite et rapide de l'innocuité, de l'efficacité réelle des vaccins et de la couverture vaccinale dans différentes populations clés, ainsi qu'une immunisation efficace et utile des populations des communautés difficiles d'accès, éloignées et isolées.

- Des efforts devraient être fournis pour améliorer les connaissances sur les bienfaits des vaccins en général et des vaccins contre la COVID-19 lorsque chacun d'entre eux sera disponible, afin de lutter contre la désinformation et de communiquer de manière transparente sur les décisions d'attribution des vaccins contre la COVID-19.

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V.I Résumé des considérations pour les vaccins contre la COVID-19 dont l'utilisation est autorisée au Canada

À l'heure actuelle, quatre types de vaccins contre la COVID-19 sont autorisés au Canada pour la prévention de l'infection à COVID-19 symptomatique qui utilisent deux plateformes vaccinales distinctes. Les mérites des deux plateformes vaccinales sont résumés dans le Tableau 5 ci-dessous. Il faut faire preuve de prudence lors de la comparaison des vaccins en raison des différences dans les études menées pour chaque vaccin (p. ex., différents paramètres, différentes analyses, différentes périodes/différents pays et différentes souches en circulation).

Tableau 5. Considérations en matière de vaccination selon les types de vaccins contre la COVID-19 dont l'utilisation est approuvée au Canada

Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
Efficacité potentielle et efficacité réelle	**Efficacité potentielle contre les infections symptomatiques après une série complète** • Le vaccin de Pfizer-BioNTech est efficace à 94 % ≥14 jours après la 2e dose chez les participants à l'étude de 16 ans et plus. Les données suggèrent que le vaccin de Pfizer/BioNTech est efficace à 95 % chez les participants de ≥65 ans et à 100 % chez les participants à l'étude de 12 à 15 ans, au même 7 jours suivant la 2e dose. • Le vaccin de Moderna est efficace à 94 % chez les participants de 18 ans et plus ≥14 jours suivant la 2e dose. • Les données suggèrent que le vaccin de Moderna est efficace à 86 % chez les personnes de ≥65 ans ≥14 jours suivant la 2e dose. **Efficacité réelle contre la maladie sévère, l'hospitalisation et le décès attribuables aux vaccins à ARNm contre la COVID-19 (avec plus de données disponibles sur le vaccin de Pfizer-BioNTech que celui de Moderna)** • Les données actuelles issues d'études en conditions réelles indiquent que les vaccins à ARNm contre la COVID-19 offrent une très bonne protection contre l'hospitalisation liée à	**Efficacité potentielle contre les infections symptomatiques après une série complète** • Le vaccin d'AstraZeneca SD/SD est efficace à 62 % chez les participants âgés de 18 à 64 ans. • Les données actuelles des essais cliniques dont insuffisantes pour déterminée l'efficacité potentielle du vaccin d'AstraZeneca chez les personnes ≥65 ans. • L'intervalle entre la première et la deuxième dose du vaccin d'AstraZeneca pourrait avoir une incidence sur l'efficacité du vaccin, l'efficacité étant moindre si l'intervalle est inférieur à 12 semaines. • Le vaccin de Janssen (1 dose) est efficace à 66,9 % et à 66,1 % contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique à ≥ 14 jours et ≥ 28 jours après la vaccination, respectivement. • Le vaccin de Janssen est efficace à 76,7 % et à 85,4 % contre l'infection à la COVID-19 symptomatique sévère/critique confirmée à ≥ 14 jours et ≥ 28 jours après la vaccination, respectivement. **Efficacité réelle contre la maladie symptomatique et l'hospitalisation**

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	la COVID-19 chez les adultes après la réponse à la première dose, y compris dans les populations plus âgées (≥ 65 ans). • Les données issues d'études en conditions réelles montrent que les vaccins à ARNm contre la COVID-19 offrent une très bonne protection contre les décès attribuables à la COVID-19 chez les adultes après la réponse à la première dose. • Des données issues d'études en conditions réelles chez les adultes indiquent que les vaccins à ARNm contre la COVID-19 offrent une excellente protection contre la maladie sévère, y compris l'hospitalisation et les décès liés à la COVID-19 après la réponse à la deuxième dose. • Les données sur l'efficacité réelle chez les adolescents de 12 à 15 ans (vaccin contre la COVID-19 de Pfizer-BioNTech) ou du vaccin contre la COVID-19 de Moderna seul ne sont pas actuellement disponibles.	• Les données d'observation chez les personnes âgées de plus de 65 ans ont montré une réduction du risque de maladie symptomatique et d'hospitalisation avec une dose du vaccin d'AstraZeneca. • Les données sur l'efficacité réelle du vaccin (dans le monde réel) contre la COVID-19 de Janssen indiquent une bonne protection contre l'infection par le SRAS-CoV2[127].
	Efficacité potentielle contre les infections asymptomatiques • Une analyse préliminaire de données limitées provenant d'un essai en cours suggère que le vaccin contre la COVID-19 de Moderna pourrait être efficace dans la prévention des infections asymptomatiques. Toutefois, les données sont en cours de collecte et l'analyse finale n'est pas achevée. **Efficacité réelle contre les infections asymptomatiques** • Les estimations de l'efficacité réelle du vaccin contre la COVID-19 de Pfizer-BioNTech contre l'infection par le SRAS-CoV-2 sans symptômes signalés étaient de modérées à élevées après la première dose (en fonction du temps écoulé depuis la vaccination) et élevées après la deuxième dose)[9, 16] chez les adultes. Des résultats similaires ont été signalés pour les vaccins à ARNm contre la COVID-19 en général [21].	**Efficacité potentielle contre les infections asymptomatiques** • Une analyse exploratoire ponctuelle de données limitées suggère que le vaccin d'AstraZeneca pourrait ne pas être efficace dans la prévention d'une infection asymptomatique. • Les analyses préliminaires des données limitées semblent indiquer que le vaccin contre la COVID-19 de Janssen a une efficacité potentielle estimée à 59,7 % contre l'infection par le SRAS-CoV-2 asymptomatique ou non détectée avec une apparition ≥ 28 jours après la vaccination.
	Revaccination	**Revaccination**

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	• Il n'est pas encore clair si des doses de rappel (p. ex., une vaccination annuelle) seront nécessaires pour assurer une protection à long terme contre la COVID-19 symptomatique, en particulier face à l'émergence de VP. • La revaccination des personnes ayant initialement reçu un vaccin à ARNm avec le même vaccin ou un autre vaccin à ARNm est actuellement à l'étude. • L'efficacité potentielle et l'innocuité de la revaccination des personnes ayant initialement reçu le vaccin à ARNm avec un vaccin contre la COVID-19 différent sont pour l'instant inconnues à l'heure actuelle mais font l'objet de recherches.	• Il n'est pas encore clair si des doses de rappel (p. ex., une vaccination annuelle) seront nécessaires pour assurer une protection à long terme contre la COVID-19 symptomatique, en particulier face à l'émergence de VP. • La revaccination avec une dose de rappel des vaccins à vecteur viral peut réduire l'efficacité réelle en raison du développement possible d'une immunité contre le vecteur viral qui peut interférer avec la réponse immunitaire aux doses ultérieures. Toutefois, cette question est toujours à l'étude. • L'efficacité potentielle et l'innocuité de la revaccination des personnes ayant initialement reçu un vaccin à vecteur viral avec un vaccin contre la COVID-19 différent sont pour l'instant inconnues.
Immunogénicité	**Réponse humorale** • Les réponses humorales pour les deux vaccins à ARNm contre la COVID-19 dans les essais cliniques atteignent leur maximum après la deuxième dose, y compris l'obtention d'anticorps neutralisants. Cependant, comme on ne connaît pas de corrélat de protection, ces réponses humorales ne peuvent pas être interprétées comme correspondant à la protection vaccinale. • Les réponses humorales dans les essais cliniques ont connu des tendances similaires chez les personnes de 18 à 55 ans et chez les personnes de 65 à 85 ans. • Les réponses humorales du vaccin de Pfizer-BioNTech chez les adolescents de 12 à 15 ans ont atteint et dépassé les niveaux observés chez les adultes de 16 à 25 ans. • Dans des études observationnelles, les réponses humorales chez les sujets vaccinés séropositifs après l'administration de la première dose étaient comparables à celles observées chez les personnes n'ayant pas été infectées par le SRAS-CoV-2 après l'administration de la deuxième dose. Toutefois, puisque le corrélat de protection est inconnu, l'importance de ces	**Réponse humorale** • Les réponses humorales pour le vaccin d'AstraZeneca dans les essais cliniques ont atteint leur maximum après une deuxième dose, y compris l'obtention d'anticorps neutralisants, chez les sujets vaccinés séronégatifs. Chez les sujets vaccinés séropositifs, les réponses humorales ont atteint leur maximum à la première dose et se sont maintenues ou ont diminué à la deuxième dose. • Pour le vaccin d'AstraZeneca, les réponses humorales dans les essais cliniques étaient plus faibles chez les personnes de ≥65 ans que chez les personnes de 18 à 64 ans, d'après des données non publiées présentées au CCNI. Des résultats contradictoires ont été constatés pour les autres groupes d'âge d'après des données récemment publiées [128]. • Dans le cas du vaccin Janssen, des réponses humorales, notamment des anticorps de liaison, des anticorps neutralisants et des anticorps ayant des fonctions effectrices Fc, ont été observées au jour 29 après une dose. • Pour ce qui est du vaccin de Janssen, des réponses immunitaires humorales un peu plus faibles ont été observées dans les cohortes d'âges plus élevés (> 65 ans) par rapport aux cohortes plus jeunes (de 18 à 55 ans).

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	conclusions quant au niveau de protection contre la réinfection est aussi inconnue [48][26][49, 50][51][52].	• Cependant, comme on ne connaît pas de corrélat de protection, ces réponses humorales ne peuvent pas être interprétées comme correspondant à la protection vaccinale.
	Réponse cellulaire • Les deux vaccins à ARNm contre la COVID-19 ont induit une réponse immunitaire à médiation cellulaire une à deux semaines après l'administration de la deuxième dose. • On a constaté une augmentation de cette réponse immunitaire à médiation cellulaire chez les jeunes adultes comme chez les adultes plus âgés. Aucune donnée n'existe sur les réponses immunitaires cellulaires chez les adolescents de 12 à 15 ans. • Comme aucun corrélat immunologique de protection n'a été déterminé pour le SRAS-CoV-2, ces réponses cellulaires ne peuvent être interprétées comme correspondant à la protection vaccinale.	**Réponse cellulaire** • Le vaccin d'AstraZeneca a induit des réponses cellulaires à médiation cellulaire qui n'ont pas semblé augmenter après la deuxième dose. • Les réponses immunitaires à médiation cellulaire ne semblent pas différer entre les groupes d'âge. • Dans le cas du vaccin Janssen, les réponses immunitaires cellulaires ont été déclenchées après une dose du vaccin. • Comme aucun corrélat immunologique de protection n'a été déterminé pour le SRAS-CoV-2, ces réponses cellulaires ne peuvent être interprétées comme correspondant à la protection vaccinale.
Protection contre les variants, y compris les variants préoccupants	**B.1.1.7 (alpha)** • Les données suggèrent une efficacité réelle comparable des vaccins à ARNm contre la COVID-19 face aux maladies symptomatiques et sévères en raison du VP B.1.1.7 (alpha). **B.1.351 (béta)** • Les données probantes émergentes suggèrent que les vaccins à ARNm contre la COVID-19 sont efficaces à 43 % contre les maladies symptomatiques en raison du VP B.1.351 (béta) après une dose et à 88 % après deux doses[19]. **P.1 (gamma) et P.2 (zêta)** • Il y a des données limitées sur l'efficacité potentielle et l'efficacité réelle des vaccins à ARNm contre le VP P.1 (gamma) et le VI P.2 (zêta).	**B.1.1.7 (alpha)** • Les données suggèrent que le vaccin contre la COVID-19 d'AstraZeneca COVID-19 a une efficacité vaccinale de 70,4 % contre le VP B.1.1.7 (alpha) identifié pour la première fois au Royaume-Uni, contre 81,5 % contre les souches non B.1.1.7 (où les cas étaient principalement attribuables à B.1.177, une souche non VI/VP) [132]. **B.1.351 (béta)** • Les données semblent indiquer que le vaccin d'AstraZeneca a une efficacité potentielle de 10,4 % contre le VP B.1.351 (béta) face à la maladie légère à modérée [133]. • En Afrique du Sud, où le VP B.1.351 (béta) était la souche dominante (environ 95 % des échantillons préliminaires séquencés), le vaccin de Janssen était efficace à 64 % contre la COVID-19 modérée à sévère/critique au jour 29.

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	B.1.617.2 (delta) • Des données émergentes suggèrent que le vaccin contre la COVID-19 de Pfizer-BioNTech est efficace à 33,2% contre la maladie symptomatique en raison du B.1.617.2 (delta) après une dose, et à 87,9% après deux doses [129]. • Contre toute infection (symptomatique ou asymptomatique) attribuable au B.1.617.2 (delta), les données émergentes suggèrent que le vaccin de Pfizer-BioNTech est efficace à 30 % après une dose et à 79 % après deux doses [130]. • Les données émergentes suggèrent que le vaccin de Pfizer-BioNTech est efficace à 94 % contre l'hospitalisation attribuable au B.1.617.2 (delta) après une dose et à 96 % après deux doses [131].	**P.1 (gamma) et P.2 (zêta)** • Il y a des données limitées sur l'efficacité potentielle et réelle des vaccins à vecteur viral contre les VP P.1 (gamma). • Au Brésil, où le P.2 (zêta) a été détecté dans environ 70 % des échantillons séquencés de cas de COVID-19, le vaccin de Janssen avait une efficacité potentielle de 68 % contre la COVID-19 modérée à sévère/critique au jour 29. **B.1.617.2 (delta)** • Des données émergentes suggèrent que le vaccin contre la COVID-19 d'AstraZeneca est efficace à 32,9 % contre la maladie symptomatique en raison du B.1.617.2 (delta) après une dose, et à 59,8 % après deux doses [129]. • Contre toute infection (symptomatique ou asymptomatique) attribuable au B.1.617.2 (delta), les données émergentes suggèrent que le vaccin d'AstraZeneca est efficace à 18 % après une dose et à 60 % après deux doses [130]. • Des données émergentes suggèrent que le vaccin d'AstraZeneca est efficace à 71 % contre l'hospitalisation attribuable au B.1.617.2 (delta) après une dose et à 92 % après deux doses [131].
Innocuité	**Technologie** • Les vaccins à ARNm utilisent une nouvelle technologie; (qui a été étudiée dans des vaccins expérimentaux); toutefois, tous les vaccins contre la COVID-19 sont soumis au même processus rigoureux d'examen et d'approbation que les vaccins systématiques.	**Technologie** • Les vaccins à vecteur viral utilisent une technologie relativement nouvelle; (le vaccin contre l'Ébola autorisé utilise cette technologie); toutefois, tous les vaccins contre la COVID-19 sont soumis au même processus rigoureux d'examen et d'approbation que les vaccins systématiques.
	Signalement en matière d'innocuité • De rares réactions anaphylactiques ont été signalées après l'immunisation par des vaccins à ARNm COVID-19. • Pour les deux vaccins, on signale que certains ÉI sollicités sont très fréquents (définis comme étant de 10 % ou plus) chez les	**Signalement en matière d'innocuité** • Pour les deux vaccins, on a signalé que certains ÉI sollicités étaient très fréquents (définis comme étant de 10 % ou plus) chez les personnes vaccinées; toutefois, ils sont légers ou modérés et transitoires et se résorbent en quelques jours. Il s'agit notamment de douleurs au site d'injection, de la fatigue, de maux de tête, de

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	personnes vaccinées; toutefois, ils sont légers ou modérés et transitoires et se résorbent en quelques jours. Il s'agit notamment de douleurs au site d'injection, de fatigue, de maux de tête, de douleurs musculaires, de frissons, de douleurs articulaires et de fièvre. Certains ÉI, dont la fièvre, sont plus fréquents après la deuxième dose. • Pour le vaccin contre la COVID-19 de Pfizer-BioNTech, comparativement aux personnes de 16 à 55 ans, les adolescents de 12 à 15 ans ont montré une fréquence accrue de maux de tête (jusqu'à 65 %), de frissons (jusqu'à 42 %) et de fièvre (jusqu'à 20 %). La lymphadénopathie chez les adolescents est survenue chez 0,8 % des sujets vaccinés (0,6 % avaient une lymphadénopathie liée à la vaccination), et aucun ÉI lié au vaccin ni aucun décès n'a été signalé. • Des cas de myocardite (inflammation du muscle cardiaque) et de péricardite (inflammation de la muqueuse autour du cœur) suivant l'administration de vaccins à ARNm contre la COVID-19 ont été signalés au Canada et à l'échelle internationale. Au Canada, nous ne constatons actuellement pas de taux plus élevés que ce à quoi on s'attendrait dans la population générale; toutefois, le nombre de deuxièmes doses administrées à un âge plus jeune est relativement faible à ce jour. Les données sur ce phénomène évoluent et les recherches sur l'association entre les vaccins contre la myocardite/péricardite et l'ARNm se poursuivent au Canada et à l'étranger. D'après les cas signalés à l'échelle internationale, les renseignements disponibles indiquent qu'ils surviennent généralement dans la semaine suivant la vaccination, le plus souvent chez les hommes et plus souvent chez les adolescents et les jeunes adultes. Les cas signalés après l'administration des vaccins à ARNm contre la COVID-19 ont généralement été bénins et ont été bien résolus grâce à un traitement médical.	douleurs musculaires, de frissons, de douleurs articulaires et de fièvre. Certains ÉI sont moins fréquents après la deuxième dose. • De rares cas de thrombose associés à la thrombocytopénie ont été signalés suivant l'administration du vaccin d'AstraZeneca. Le mécanisme d'action semble être similaire à une thrombocytopénie induite par l'héparine spontanée (appelée TTIV – thrombocytopénie thrombotique immunitaire induite par le vaccin). À l'échelle internationale, le taux de cet ÉI n'est pas encore confirmé mais avait été le plus souvent estimé entre 1/26 000 et 1/100 000 personnes ayant reçu le vaccin d'AstraZeneca. Selon les données probantes disponibles au 1 juin 2021, l'ASPC a estimé le taux des TTIV au Canada à 1 par 73 000 doses administrées. Toutefois, à mesure que les investigations se poursuivent, ce taux pourrait s'élever à 1 par 50 000. Le taux de létalité se situe généralement entre 20 et 50 %. Les autres facteurs prédisposant à la TTIV ne sont pas clairs. • Pour le vaccin de Janssen, dans l'essai clinique, un cas de CVST a été signalé parmi 21 895 sujets vaccinés. En date du 24 mai 2021, 32 case de STT ont été confirmés après l'administration d'environ 10,2 millions de doses de Janssen aux É.-U. Des investigations sont en cours. • De très rares cas de SFC ont été signalés après l'administration du vaccin contre la COVID-19 d'AstraZeneca. Certains patients affectés ont reçu un diagnostic antérieur de SFC qui constitue une affection grave et potentiellement mortelle caractérisée par des épisodes aigus d'œdème des membres, d'hypotension, d'hémoconcentration et d'hypoalbuminémie. Les personnes ayant des antécédents de SFC ne devraient pas recevoir le vaccin contre la COVID-19 d'AstraZeneca/COVISHIELD.

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
Éthique et équité	• Les vaccins à ARNm ont une grande efficacité à court terme dans tous les groupes d'âge autorisés et le Canada prévoit d'avoir suffisamment de doses de vaccins à ARNm pour chaque personne au Canada en 2021. • Les vaccins les plus efficaces peuvent être dirigés vers les personnes les plus susceptibles de contracter une maladie sévère et d'être exposées afin de limiter l'aggravation des inégalités existantes. • L'incidence de ne pas offrir un vaccin moins efficace plus tôt aux populations qui devront attendre pour recevoir un vaccin à ARNm dans les zones de de transmission et d'infection à haut risque sur la confiance, la justice et le risque de faire plus de mal que de bien devrait être prise en compte.	• Offrir un vaccin contre la COVID-19 à ceux qui devraient autrement attendre pour en recevoir un pourrait renforcer l'équité. • Si la protection contre la COVID-19 ne peut être augmentée pour les personnes qui ont reçu un vaccin moins efficace en premier, des inégalités importantes pourraient être créées pour les personnes qui reçoivent un vaccin à vecteur viral par rapport à un vaccin à ARNm, dépendamment des groupes de populations qui ont reçu le vaccin à vecteur viral. • Les vaccins à vecteur viral peuvent offrir une option aux personnes allergiques aux ingrédients du vaccin à ARNm ou de ses contenants. L'incidence de l'offre d'un vaccin moins efficace plus tôt à certaines populations sur la confiance, la justice et le risque de faire plus de mal que de bien devrait être prise en compte.
Faisabilité	**Calendrier de vaccination** • Les deux vaccins à ARNm sont administrés en deux doses. • Les vaccins à ARNm ont un calendrier autorisé de 21 (pour le vaccin de Pfizer) ou de 28 jours (pour le vaccin de Moderna) entre la première et la deuxième dose. Bien que le CCNI recommande actuellement un intervalle prolongé jusqu'à 4 mois entre les première et deuxième doses des vaccins contre la COVID-19 pour tous les groupes d'âge autorisés afin de maximiser le nombre de personnes bénéficiant de la première dose, les approvisionnements actuels de vaccins contre la COVID-19 prennent désormais en charge des intervalles plus courts entre les doses.	**Calendrier de vaccination** • Le vaccin d'AstraZeneca est administré en deux doses. L'intervalle entre la première et la deuxième dose du vaccin d'AstraZeneca semble avoir une incidence sur l'efficacité du vaccin, l'efficacité étant moindre si l'intervalle est inférieur à 12 semaines. Bien que le CCNI recommande actuellement un intervalle prolongé jusqu'à 4 mois entre les première et deuxième doses des vaccins contre la COVID-19 pour tous les groupes d'âge autorisés afin de maximiser le nombre de personnes bénéficiant de la première dose, les approvisionnements actuels de vaccins contre la COVID-19 prennent désormais en charge des intervalles plus courts entre les doses. • L'utilisation du vaccin de Janssen est autorisée en une seule dose, ce qui peut faire accroître la faisabilité de l'achèvement d'une série de vaccins. • Les sujets vaccinés doivent être informés du signalement en matière d'innocuité de la TTIV et des symptômes à surveiller après la vaccination.
	Exigences en matière d'entreposage	**Exigences en matière d'entreposage**

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	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	• Les vaccins à ARNm ont des exigences plus strictes en matière de transport et d'entreposage, puisqu'ils nécessitent des chaînes du froid congelées ou ultracongelées. Des efforts importants ont été entrepris pour traiter des complexités logistiques. Les exigences en matière d'entreposage de ces vaccins augmentent la complexité logistique de l'offre de ces vaccins en divers lieux afin d'en accroître l'accès pour diverses populations.	• Les vaccins à vecteur viral sont plus faciles à transporter, à entreposer et à manipuler que les vaccins à ARNm et, par conséquent, pourrait être plus facile à utiliser pour une distribution plus large par l'intermédiaire des pharmacies et des fournisseurs de soins de santé primaires. • Les vaccins à vecteur viral doivent être entreposé et transporté à une température comprise entre +2 et +8 °C, ce qui nécessite l'utilisation d'une infrastructure de chaîne du froid standard largement disponible dans les provinces et territoires. • Les exigences en matière d'entreposage de ces vaccins pourraient accroître l'accès au vaccin pour diverses populations.
Acceptabilité	• Il est possible que les individus favorisent les vaccins à ARNm, car leur efficacité avérée est plus grande. • Des cas de COVID-19 moindres sont prévus à la suite d'une vaccination avec un vaccin à haute efficacité. Les cas relativement faibles après la vaccination pourraient avoir une incidence positive sur l'acceptabilité des vaccins contre la COVID-19 et des vaccins en général.	• Il est possible que des personnes favorisent les vaccin à vecteur viral s'ils offrent une possibilité de recevoir plus tôt un vaccin contre la COVID-19 et s'ils sont plus faciles d'accès sur des lieux convenables en raison de la facilité de transport, d'entreposage et de manipulation. • Un nombre accru de cas de COVID-19 est prévu à la suite d'une vaccination avec un vaccin qui a une efficacité moindre. Les cas relativement élevés après la vaccination pourraient avoir une incidence négative sur l'acceptabilité par le public des vaccins contre la COVID-19 et des vaccins en général. • Le vaccin Janssen est administré en une seule dose. Cela pourrait accroître l'acceptabilité de la vaccination. • Des cas récents de TTIV signalés après l'administration des vaccins à vecteur viral ont influé sur leur acceptabilité.
	Les inquiétudes concernant l'innocuité et l'efficacité réelle des vaccins sont les deux raisons les plus souvent citées pour justifier le refus d'un vaccin [134] • Dans une enquête menée auprès des Canadiens entre le 9 et le 16 février 2021 [135], les résultats suivants ont été rapportés : ○ De ceux qui ont indiqué ne pas encore avoir été vaccinés (n = 1954), un plus grand nombre de répondants étaient « d'accord » ou « tout à fait d'accord » avec les énoncés affirmant une intention d'obtenir un « vaccin sûr » (69 %) et un « vaccin efficace » (67 %) depuis la quatrième vague (fin mai-début juin). ○ Lorsque l'on a demandé aux répondants qui étaient disposés à se faire vacciner ou neutres à l'égard de la vaccination ce qui était le plus important dans le choix d'un vaccin contre la COVID-19 (n = 1595), 46 % ont choisi « Recevoir le vaccin le plus	

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Facteur à prendre en considération	Résumé des données probantes disponibles et des points à prendre en compte	
	Vaccins à ARNm contre la COVID-19	**Vaccins à vecteur viral non réplicatif contre la COVID-19**
	efficace », 15 % ont choisi « Recevoir n'importe quel vaccin dès que possible » et 12 % ont choisi « Recevoir le vaccin pour lequel le moins d'effets secondaires ont été signalés ». Le nombre de doses et le type de technologie vaccinale n'étaient pas des facteurs importants, et 14 % des répondants ont indiqué qu'ils n'avaient aucune préférence pour un vaccin contre la COVID-19 en particulier. ○ Pour ceux qui attendront pour se faire vacciner même une fois le vaccin disponible : 80 % attendront afin de s'assurer de l'innocuité du vaccin, 64 % attendront afin de s'assurer de l'efficacité réelle du vaccin (n = 691) [136]. • Dans un sondage mené du 4 au 13 décembre 2020 [137] auprès des prestataires de soins de santé, les facteurs les plus importants qui ont été signalés comme influant sur la décision de se faire vacciner étaient l'innocuité du vaccin (95,5 %), suivie de l'efficacité réelle du vaccin (86,7 %) (n = 14 336)	

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VI. PRIORITÉS EN MATIÈRE DE RECHERCHE

La COVID-19 et les vaccins connexes sont nouveaux; il existe donc de nombreux domaines dans lesquels des recherches s'imposent. Les recherches visant à répondre aux questions en suspens suivantes (non classées par ordre d'importance) en s'appuyant sur des données à court et à long terme, lorsqu'elles sont disponibles, sont encouragées :

Nouvelles priorités de recherche

Efficacité potentielle, efficacité réelle, immunogénicité et innocuité

1. Quelles sont l'efficacité réelle pour la population (contre l'infection/la transmission, l'hospitalisation et la mort) et la durabilité de protection à moyen et long terme d'une dose unique ou d'une série complète de chaque vaccin contre la COVID-19 approuvé au Canada?
2. Quelles sont l'utilité, l'efficacité potentielle, l'efficacité réelle, l'immunogénicité et l'innocuité des vaccins contre la COVID-19 dans divers groupes de population (p. ex. les adultes d'âge avancé, les personnes atteintes d'affections à haut risque, y compris les personnes atteintes d'affections auto-immunes et les receveurs de greffes, et les individus socialement ou professionnellement vulnérables, les personnes enceintes ou qui allaitent, les enfants/adolescents, les personnes fragiles)? Une troisième dose de rappel du vaccin ou une dose plus élevée de vaccin est-elle nécessaire pour obtenir une réponse immunitaire appropriée chez les personnes?
3. Quelles sont l'efficacité potentielle, l'efficacité réelle, l'immunogénicité et l'innocuité des vaccins contre la COVID-19 chez les personnes qui ont déjà été atteintes d'une infection par le SRAS-CoV-2 confirmée en laboratoire?
    a. Y a-t-il une différence perceptible entre les personnes séronégatives et séropositives dans l'un des paramètres ci-dessus?
    b. Une exposition antérieure au SRAS-CoV-2 a-t-elle une incidence sur l'utilité, l'efficacité potentielle, l'efficacité réelle, l'immunogénicité ou l'innocuité des vaccins contre la COVID-19?
    c. Un vaccin à dose unique peut-il être aussi efficace et sûr chez les personnes atteintes antérieurement d'une forme avérée de COVID-19?
    d. Y a-t-il des signalements en matière d'innocuité émergents associés à l'immunisation contre la COVID-19 que la compréhension actuelle du profil d'innocuité de vaccins similaires ne permet pas de prévoir?
    e. La vaccination d'individus avec ou sans infection antérieure par le SRAS-CoV-2 risque-t-elle de provoquer une aggravation ou une modification de la maladie lors d'une infection ultérieure par le SRAS-CoV-2 ou d'autres coronavirus endémiques?
4. Quelles sont l'efficacité potentielle, l'efficacité réelle, l'immunogénicité et l'innocuité des vaccins contre la COVID-19 (y compris les rappels potentiels) contre les VP du SRAS-CoV-2?
5. Quel est le corrélat de la protection contre le SRAS-CoV-2? En quoi les réponses immunitaires attribuables à une infection naturelle sont-elles similaires ou différentes de

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celles qui sont provoquées par les vaccins contre la COVID-19? L'infection naturelle par le SRAS-CoV-2 (symptomatique ou asymptomatique) est-elle associée à une protection contre une réinfection ou une forme sévère de la maladie?

6. D'autres données probantes immunologiques sont nécessaires dans les domaines suivants afin d'éclairer les prévisions de l'efficacité :

    a. Comment les réponses immunitaires évoluent-elles dans le temps? Quelle est la durabilité des réponses immunitaires contre le SRAS-CoV-2 à long terme? Quelle est l'incidence de la dose ou de l'intervalle de vaccination sur la durabilité?
    b. Quelles sont les réponses immunitaires les plus importantes pour la protection contre l'infection (immunité adaptative ou innée), la maladie sévère ou la transmissibilité? Quel est le rôle de l'immunité humorale par rapport à l'immunité cellulaire dans la prévention de l'échappement des variants viraux au système immunitaire? Quelle est l'ampleur minimale de la réponse anticorps nécessaire à la protection?
    c. Les anticorps de classe immunoglobuline (IgA/IgG/IgM) protègent-ils contre le SRAS-CoV-2, et quel est le corrélat de protection?

7. Quel niveau de couverture vaccinale contre la COVID-19 est nécessaire pour atteindre les différentes étapes de santé publique, notamment : une couverture permettant de réduire la charge du système de santé à un niveau gérable, l'obtention d'une immunité collective pour protéger les personnes non vaccinées et la suppression des contrôles liés aux mesures de santé publique? Quelles sont les caractéristiques du vaccin qui jouent le rôle le plus important concernant ces étapes (c'est-à-dire efficacité, durabilité, adoption)?

8. Quel est le niveau de fond des réponses canadiennes spécifiques aux vecteurs vaccinaux (c'est-à-dire anti-AdCh)? Ces réponses sont-elles plus élevées dans certains groupes? Ces réponses vont-elles nuire à l'efficacité du vaccin chez ces groupes hautement séropositifs? Quelle est la durée de l'immunité anti-interférences des vecteurs après l'administration de vaccins à vecteurs viraux?

9. Comment les variants viraux influeront-ils sur l'utilité, l'efficacité potentielle, l'efficacité réelle, l'immunogénicité et l'innocuité d'un vaccin en ce qui concerne la mort, la maladie sévère, la maladie symptomatique, la maladie asymptomatique, l'infectiosité et la transmission? Quel est l'effet de l'utilisation de vaccins de rappel contenant des antigènes hétérologues et quel est le moment optimal pour la vaccination de rappel?

10. Certains composants de vaccins contre la COVID-19 risquent-ils fortement de provoquer une réaction anaphylactique?

11. Quelle est l'incidence des ESSI rares et graves après l'administration des vaccins contre la COVID-19?

    a. Quelle est la fréquence de la thrombose et de la thrombocytopénie, y compris les CVST et les CID (coagulation intravasculaire disséminée) suivant la vaccination contre la COVID-19 et après l'infection par le SRAS-CoV-2? Quel est l'élément déclencheur du développement de cet ÉI à la suite d'une vaccination et que peut-on faire pour atténuer son développement?

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b. Quel est le mécanisme biologique exact par lequel les vaccins à vecteur viral peuvent déclencher un TTIV? La TTIV est-elle un effet de classe des vaccins à vecteur adénoviral ou existe-il des mécanismes distincts qui sont spécifiques au produit (p. ex., en raison des doses différentes ou de l'importance de la réponse immunitaire selon la nature des vaccins)?

c. De quelle façon l'âge, le sexe ou autres caractéristiques du patient (p. ex., grossesse, comportements favorables à la santé) affectent-ils la fréquence de la TTIV et de ses complications?

12. Y a-t-il une association entre les vaccins contre la myocardite/péricardite et l'ARNm contre la COVID-19? Si oui, quel est le mécanisme biologique par lequel les vaccins à ARNm peuvent déclencher une myocardite/péricardite? Comment l'âge, le sexe, d'autres caractéristiques du patient ou le calendrier de vaccination affectent-il l'incidence de la myocardite/péricardite après l'administration des vaccins contre la COVID-19?

13. Les antécédents d'infection par un coronavirus endémique ont-ils un impact sur l'évolution de la maladie du SRAS-CoV-2? Existe-t-il une protection croisée ou une interférence des anticorps ou de l'exposition aux coronavirus saisonniers humains en cas d'exposition au SRAS-CoV-2 ou de vaccination contre le SRAS-CoV2?

14. Y a-t-il des interactions négatives entre la vaccination contre la COVID-19 et d'autres médicaments? Quel est l'intervalle recommandé entre les vaccins contre la COVID-19 et les anticorps prophylactiques ou thérapeutiques anti-SRAS-CoV-2 ou le plasma de convalescents?

15. La vaccination a-t-elle une incidence sur la transmissibilité du SRAS-CoV-2 chez les personnes atteintes d'une infection asymptomatique?

16. Quel est le rôle de l'atténuation saisonnière du SRAS-CoV-2?

17. Quelle est l'incidence de la vaccination sur la variation de la transmission au niveau individuel (p. ex., les superpropagateurs)?

18. Quelle est l'épidémiologie des VP du SRAS-CoV-2 dans le temps et dans le pays et ses régions? Quelles sont la transmissibilité et la virulence (y compris les hospitalisations et les décès) des VP du SRAS-CoV-2?

19. Quelles sont les caractéristiques épidémiologiques de la survenue de l'infection (p. ex., caractéristiques des personnes vaccinées, VP)?

Administration des vaccins

20. Quelles sont l'efficacité potentielle, l'efficacité réelle, l'immunogénicité et l'innocuité d'un calendrier de doses mixtes ou d'une série de doses de rappel mixtes?

21. Quels sont les intervalles minimum, maximum et optimal entre les doses d'un vaccin contre la COVID-19 comprenant un calendrier à deux doses qui continuent à assurer une protection contre la maladie?

22. D'autres vaccins (p. ex., le bacille de Calmette-Guérin) protègent-ils contre la COVID-19 par des effets non ciblés?

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23. Les vaccins contre la COVID-19 peuvent-ils être administrés simultanément avec d'autres vaccins qui ne sont pas contre la COVID-19 (vaccins vivants ou inactivés)? Quel est l'intervalle minimum entre l'administration d'un vaccin contre la COVID-19 et d'autres vaccins non-COVID-19 (vaccins vivants ou inactivés)? Quels sont les résultats immunologiques et cliniques si les vaccins contre la COVID-19 étaient administrés simultanément avec d'autres vaccins non-COVID-19?

24. Quel est l'intervalle minimum requis pour l'administration du vaccin après l'administration de plasma de convalescents ou d'anticorps monoclonaux neutralisant la protéine de spicule du SRAS-CoV-2?

Priorités de recherche permanentes

Infection par la COVID-19 et maladie

1. Quel est le profil épidémiologique de la COVID-19 (p. ex., la période de transmissibilité, tous les groupes à risque)?

    a. Quelle est la répartition de la maladie et le spectre de la maladie clinique pour la COVID-19, y compris la morbidité et le risque en fonction de l'âge, du sexe et d'autres variables démographiques associées à un risque accru?
    b. Quelles sont les dynamiques de transmission de la COVID-19, y compris le degré de transmission asymptomatique, le rôle des enfants dans la transmission, la transmissibilité verticale, le début et la durée de l'excrétion virale et de la période de transmissibilité, les effets des conditions météorologiques changeantes et les tendances au fil du temps?
    c. Quels sont les taux de co-infection par la COVID-19 avec d'autres agents pathogènes des voies respiratoires, et quels sont les effets sur la pathogénie et les résultats cliniques?

2. Les vaccins contre la COVID-19 peuvent-ils être utilisés pour protéger les contacts familiaux d'un cas? La vaccination contre la COVID-19 diminue-t-elle l'infectiosité et la maladie clinique chez les individus qui ont déjà contracté l'infection? La vaccination contre la COVID-19 est-elle efficace pour interrompre la transmission?

Éthique, équité, faisabilité et acceptabilité

3. Quelle est l'acceptabilité (a) des vaccins contre la COVID-19 et (b) d'autres vaccins financés par des fonds publics au fil du temps et dans différents contextes épidémiologiques parmi les principales populations, les populations marginalisées, les fournisseurs et les décideurs à l'échelle du pays?
    a. Quels facteurs influent sur l'acceptabilité de la vaccination contre la COVID-19 dans ces groupes?
    b. Quels facteurs influent sur l'acceptabilité de la vaccination en général?
    c. Comment l'acceptabilité des principales populations prioritaires à immuniser en premier par les vaccins contre la COVID-19 évoluera-t-elle dans différents contextes épidémiologiques dans tout le pays?
    d. Quelles stratégies peuvent améliorer l'acceptabilité d'un vaccin contre la COVID-19 dans ces groupes?

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4. Comment les décisions relatives à l'attribution des vaccins peuvent-elles être communiquées aux personnes et aux communautés afin de maintenir la confiance dans les autorités de santé publique?
5. Quelles stratégies de vaccination contre la COVID-19 ou stratégies de mise en œuvre peuvent réduire les inégalités en matière de santé dans des populations auxquelles le programme de vaccination s'adresse directement, et dans des populations auxquelles le programme de vaccination ne s'adresse pas, mais qui en sont encore affectées (p. ex., la maladie, les effets indirects comme pour les soignants ou les effets externes comme l'immunité collective)?
6. Un autre vaccin contre la COVID-19 peut-il être utilisé pour compléter une série primaire ou pour faire office de dose de rappel? Comment les voyageurs de retour au pays sont-ils pris en charge s'ils ont commencé, mais n'ont pas terminé une série de vaccins contre la COVID-19 à l'étranger?

Qualité de vie liée à la santé et bien-être

7. Quels sont la qualité de vie liée à la santé ou le bien-être des patients atteints de la COVID-19 et des soignants au fil du temps (p. ex., services publics de santé, résultats déclarés par les patients, mesures des expériences déclarées par les patients)?
8. Quel est l'impact de la vaccination contre la COVID-19 sur la qualité de vie liée à la santé ou sur le bien-être des individus?

VII. QUESTIONS LIÉES À LA SURVEILLANCE

La collecte de données, l'analyse, l'interprétation et la diffusion opportune continues et systématiques sont fondamentales pour planifier, mettre en œuvre, évaluer et prendre des décisions fondées sur des données probantes. Pour appuyer de tels efforts, le CCNI encourage l'amélioration de la surveillance dans les domaines suivants :

1. Épidémiologie

- Améliorer les données sociales et socio-économiques recueillies et mises à disposition pour comprendre et traiter les iniquités en matière de santé liées à la COVID-19.
- Procéder à un examen systématique du fardeau et de l'épidémiologie des éclosions de COVID-19 au Canada, en fonction du milieu et de la gravité, en déterminant les activités, les milieux et les populations à haut risque.
- Évaluer le succès des mesures d'intervention de santé publique visant à réduire au minimum ou à prévenir les éclosions de COVID-19, en particulier dans les communautés vulnérables ou à haut risque.

2. Travaux de laboratoire (p. ex., caractérisation des souches)

- Renforcer la surveillance en laboratoire afin de lancer des alertes rapides en cas d'augmentation ou de diminution de l'activité par âge, sexe et présence de symptômes, et aider à interpréter les données relatives aux cas en fonction des modifications apportées aux algorithmes de dépistage.

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- Mener une surveillance génomique pour détecter la transmission internationale et interprovinciale et les souches/variants nouveaux dont la gravité, la transmissibilité ou la comparabilité des vaccins sont différentes.
- Explorer d'autres trousses de détection délocalisée du SRAS-CoV-2 avec obtention immédiate des résultats.

3. Vaccin (couverture, efficacité réelle, innocuité)

- Surveiller de manière fiable les taux de couverture pour chaque vaccin contre la COVID-19 autorisé dans différentes populations principales, en veillant à obtenir des données sur l'achèvement des séries.
- Veiller à ce que les mécanismes existants d'évaluation des ÉI soient positionnés de manière à générer des données pour chaque vaccin contre la COVID-19 autorisé.

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TABLEAUX

Tableau 6. Force des recommandations du CCNI

Force de la recommandation du CCNI *Fondée sur des facteurs qui ne se limitent pas à la force des données probantes* (p. ex., besoin en santé publique)	**FORTE**	**Discrétionnaire**
Libellé	« *devrait/ne devrait pas* être réalisée »	« *peut/peut ne pas* être réalisée »
Justifications :	Les avantages connus/attendus l'emportent sur les inconvénients connus/attendus (« devrait »); OU les inconvénients connus/attendus l'emportent sur les avantages connus/attendus (« ne devrait pas »).	Les avantages connus/attendus sont à peu près équivalents aux inconvénients connus/attendus OU les données probantes n'indiquent pas avec certitude les avantages et les inconvénients.
Conséquence	Une recommandation forte s'applique à la plupart des populations/personnes et devrait être suivie, à moins qu'il n'existe une justification claire et convaincante d'utiliser une autre approche.	Une recommandation discrétionnaire peut être offerte ou non pour certaines populations/personnes dans certaines circonstances. D'autres approches peuvent être acceptables.

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LISTE DES ABRÉVIATIONS

Abréviation	*Terme*
Ad26	Adénovirus humain modifié de type 26
AdCh	Adénovirus du chimpanzé
ARCHE	Alberta Research Center for Health Evidence
ASPC	Agence de la santé publique du Canada
ARNm	Acide ribonucléique messager
CCI	Comité canadien sur l'immunisation
CCNI	Comité consultatif national de l'immunisation
COVID-19	Maladie à coronavirus 2019
CSO	Classes de système d'organe
CVST	Thrombose des sinus veineux cérébraux
DART	Developmental and Reproductive Toxicity
DS	Dose standard
ÉÉFA	Éthique, équité, faisabilité et acceptabilité
ÉI	Évènement indésirable
ÉIG	Évènement indésirable grave
ÉI sévère	Évènement indésirable sévère
EMA	Agence européenne des médicaments
ESSI	Effet secondaire suivant l'immunisation
É.-U.	États-Unis
FDA	Food and Drug Administration, États-Unis
GCI	Guide canadien d'immunisation
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IC	Intervalle de confiance
IM	Intramusculaire
MenACWY	Vaccin méningococcique quadrivalent
OCDE	Organisation de coopération et de développement économiques
OMS	Organisation mondiale de la Santé
PCR	Réaction en chaîne de la polymérase
PF4	Facteur plaquettaire 4
R.-U.	Royaume-Uni
SFC	Syndrome de fuite capillaire

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SII	Serum Institute of India
SRAS-CoV-2	Coronavirus du syndrome respiratoire aigu sévère 2
TCT	Test cutané à la tuberculine
TIPIV	Thrombocytopénie immunitaire prothrombotique induite par le vaccin
TLIG	Test de libération de l'interféron gamma
TTIV	Thrombocytopénie thrombotique immunitaire induite par le vaccin
STT	Syndrome de thrombose avec thrombocytopénie
USI	Unité de soins intensifs
VIH	Virus de l'immunodéficience humaine
VI	Variant d'intérêt
VP	Variant préoccupant

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REMERCIEMENTS

La présente déclaration a été préparée par : SJ Ismail, K Young, MC Tunis, A Killikelly, R Stirling, O Baclic, J Zafack, M Salvadori, N Forbes, L Coward, C Jensen, R Krishnan, NK Abraham, Y-E Chung, B Warshawsky, E Wong, K Farrah, A Nam, C Quach, S Deeks et C Quach au nom du Groupe de travail sur les vaccins contre les maladies infectieuses à haut risque du CCNI et a été approuvée par le CCNI.

Le CCNI remercie vivement les personnes suivantes pour leur contribution : C Quach, C Mauviel, K Ramotar, N St-Pierre, V Ferrante, S Pierre, E Tice, A Sinilaite, MW Yeung, L Whitmore, J Shurgold, J Vachon, J Macri, J Mielczarek, R Goddard, B Sader, M Patel et A House, ainsi que Alberta Research Centre for Health Evidence et le Groupe consultatif en matière d'éthique en santé publique de l'ASPC.

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ANNEXE A : RÉSUMÉ DES DONNÉES PROBANTES DES ESSAIS CLINIQUES POUR LE VACCIN CONTRE LA COVID-19 DE PFIZER-BIONTECH

L'étude C4591001 est l'essai pivot de Phases 1/2/3 pour le vaccin contre la COVID-19 de Pfizer-BioNTech. Des données probantes sur l'immunogénicité sont disponibles pour les participants de 12 à 15 ans, de 16 à 55 ans et de 65 à 85 ans. Des données probantes sur l'innocuité et l'efficacité du vaccin sont disponibles pour les adolescents de 12 à 15 ans et pour les adultes de 16 ans et plus. Les études n'ont pas inclus de participants provenant d'établissements de soins de longue durée. Les Phases 2/3 de l'essai ont porté sur environ 46 000 participants randomisés (1:1) qui ont reçu soit le vaccin, soit un placebo. Les données présentées ci-dessous sont destinées à une analyse provisoire. Par conséquent, la durée du suivi n'est pas uniforme, mais était inférieure à quatre mois après la deuxième dose (maximum de 14 semaines) pour tous les participants.

Des données probantes provenant des essais de Phases 2/3 en cours (participants de 16 ans et plus[138] et chez les adolescents de 12 à 15 ans [126]) ont été publiées en décembre 2020 et en mai 2021, respectivement, après avoir été examinées par le CCNI. Les données probantes tirées de la surveillance et des études post-commercialisation se trouvent dans le corps de la présente déclaration.

Efficacité

Complications sévères liées à la COVID-19

Il n'existe pas de données sur l'efficacité concernant les hospitalisations et les décès en particulier, mais il existe des données sur l'efficacité contre les complications sévères liées à la COVID-19, définies comme la COVID-19 confirmée en laboratoire présentant l'une des caractéristiques supplémentaires suivantes : signes cliniques au repos indicateurs d'une maladie systémique sévère; insuffisance respiratoire; signes de choc; dysfonctionnement rénal, hépatique ou neurologique aigu important; admission à l'USI ou décès [139].

Il peut y avoir un effet protecteur contre les complications sévères liées à la COVID-19 chez les personnes de 16 ans et plus lorsqu'ils reçoivent au moins une dose de vaccin (efficacité globale du vaccin de 88,9 %, IC à 95 % : de 20,1 à 99,7 %), sur la base d'un cas répertorié dans le groupe recevant le vaccin (N = 21 669) et de neuf cas dans le groupe placebo (N = 21 686). L'efficacité du vaccin contre la COVID-19 sévère a également été examinée après l'administration de la deuxième dose (à partir de 7 jours et 14 jours après la deuxième dose), mais le nombre d'évènements signalés était insuffisant (une complication sévère dans le groupe recevant le vaccin et trois dans le groupe placebo pour chaque complication) pour déterminer si le vaccin était efficace pour réduire les complications sévères avec une précision quelconque (c.-à-d. que les estimations ponctuelles qui en découlaient étaient associées à de larges intervalles de confiance, incluant zéro).

Chez les adolescents de 12 à 15 ans, l'efficacité potentielle du vaccin n'a pas pu être évaluée contre des complications sévères, car aucun cas de COVID-19 sévère n'avait été confirmé à la

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date d'analyse des données sur l'efficacité potentielle. De plus, aucun décès n'a été identifié chez les participants adolescents à l'étude pendant l'essai clinique [126].

COVID-19 symptomatique

Chez les adultes de 16 ans et plus :
L'efficacité estimée du vaccin au moins sept jours après la deuxième dose était de 94,6 % (IC à 95 % : de 89,9 à 97,3 %), 9 cas symptomatiques de COVID-19 ayant été confirmés, selon la définition du protocole de l'essai [138] parmi les sujets qui ont reçu le vaccin (N = 19 965) par rapport à 169 cas parmi les sujets qui ont reçu le placebo (N = 20 172). L'efficacité du vaccin au moins 14 jours après la deuxième dose dans cette population était comparable (94,4 %, IC à 95 % : de 89,1 à 97,3 %). Les résultats étaient similaires lorsqu'on a estimé l'efficacité expressément chez les individus sans preuve d'une infection antérieure confirmée par le SRAS-CoV-2 à 95,0 % (IC à 95 % : de 90,3 à 97,6 %), 8 cas ayant été confirmés parmi les sujets qui ont reçu le vaccin (N = 18 198) par rapport à 162 cas parmi les sujets qui ont reçu le placebo (N = 18 325).

Lorsque les participants adultes à l'étude sans preuve d'une infection antérieure par le SRAS-CoV-2 ont été stratifiés par âge, l'efficacité du vaccin contre la COVID-19 à partir de sept jours après la deuxième dose se situait entre 93,7 % (de plus de 55 ans) et 95,6 % (de 16 à 55 ans). Chez les personnes de 65 ans et plus, le taux d'efficacité du vaccin s'est établi à 94,7 % (IC à 95 % : 66,7 à 99,9 %), tandis que l'efficacité observée du vaccin chez les participants de 75 ans et plus a été de 100 % comparativement au placebo, mais avec de grands intervalles de confiance [y compris zéro] attribuable au nombre insuffisant d'évènements signalés (0 contre 5 cas; IC à 95 % : -13,1 à 100,0 %). L'efficacité estimée d'un vaccin contre la COVID-19 confirmée sept jours après la deuxième dose était supérieure à 91 % (entre 91,7 % et 100,0 %) dans tous les sous-groupes stratifiés par état « à risque » (p. ex., présence d'une ou plusieurs comorbidités). L'efficacité estimée du vaccin contre la COVID-19 confirmée dans les sept jours suivant la deuxième dose était supérieure à 89 % pour toutes les races (de 89,3 % à 100 %) et à 94 % pour toutes les ethnies incluses dans la sous-analyse (de 94,4 % à 95,4 %).

Après la première dose mais avant l'administration de la deuxième dose, 39 cas de COVID-19 ont été signalés dans le groupe du vaccin (n = 21 669), comparativement à 82 dans le groupe placebo (n = 21 686), pour une efficacité globale du vaccin estimée chez les participants de 16 ans et plus à 52,4 % (IC à 95 % : 29,5 à 68,4 %). Si on limite l'analyse aux cas identifiés seulement dans la période comprise entre le 15e jour après la première dose et avant la deuxième dose, l'efficacité estimée du vaccin passe à 92,3 % (IC à 95 % : 69 à 98 %).

Tableau 7. Efficacité du vaccin de Pfizer-BioNTech contre la première apparition de la COVID-19 symptomatique après la première dose mais avant la deuxième dose chez les participants de 16 ans et plus[a]

Période d'intérêt	Évènements dans le groupe du vaccin (N = 21 669)	Évènements dans le groupe placebo (N = 21 686)	Estimation de l'efficacité du vaccin (IC à 95 %)
Après la première dose mais avant la deuxième dose	39	82	52,4 % (29,5 à 68,4 %)
Plus de 14 jours après la première dose mais	2	27	92,3 % (69 à 98 %)

COVID-19 Vaccine

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avant la deuxième dose[b]			

[a] Dans la population d'efficacité totale disponible, composée de participants à l'étude randomisée qui ont reçu au moins une dose de l'intervention d'étude (vaccin ou placebo).

[b] Comité sur l'immunisation du Québec. Stratégie de vaccination contre la COVID-19 : report de la 2e dose en contexte de pénurie. Institut national de Santé publique du Québec, 18 décembre 2020

Chez les adolescents de 12 à 15 ans :
Chez les participants à l'étude sans preuve préalable d'une infection par le SRAS-CoV-2, aucun cas de COVID-19 n'a été confirmé au moins 7 jours suivant la deuxième dose chez les vaccinés (n = 1 005) par rapport aux 16 cas du groupe placebo (n = 978) avec une efficacité potentielle estimée du vaccin contre la COVID-19 confirmée à 100 % (IC à 95 % : 75,3 à 100 %) [126].

Après la première dose mais avant l'administration de la deuxième dose, trois (3) cas de COVID-19 ont été identifiés dans le groupe vacciné (n = 1 131) par rapport à 12 cas dans le groupe placebo (n = 1 129) avec une efficacité potentielle estimée globale du vaccin chez les adolescents de 12 à 15 ans de 75 % (IC à 95 % : 7,4 à 95,5 %. Si l'analyse avait été limitée aux cas identifiés seulement dans la période de 11 jours ou plus après la première dose mais avant la deuxième dose, l'efficacité estimée du vaccin a augmenté à 100 % (IC à 95 % : 41,4 à 100 %).

Tableau 8. Efficacité du vaccin de Pfizer-BioNTech contre la première apparition de la COVID-19 symptomatique après la première dose mais avant la deuxième dose chez les adolescents de 12 à 15 ans[a]

Période d'intérêt	Évènements dans le groupe vacciné (N = 1 131)	Évènements dans le groupe placebo (N = 1 129)	Estimation de l'efficacité du vaccin (IC à 95 %)
Après la première dose mais avant la deuxième dose	3	12	75 % (7,4 to 95,5 %)
≥11 jours après la première dose mais avant la deuxième dose	0	8	100 % (41,4 to 100 %)

[a] Dans la population d'efficacité totale disponible, composée de participants à l'étude randomisée qui ont reçu au moins une dose de l'intervention d'étude (vaccin ou placebo).

Aucune analyse n'est fournie pour l'efficacité expressément chez les personnes (de tout âge) avec preuve d'une infection antérieure par le SRAS-CoV-2.

Infection asymptomatique et transmission
Il n'existe pas de données sur l'efficacité pour ces résultats à l'heure actuelle.

Immunogénicité

Réponses immunitaires humorales
Les anticorps de liaison et de neutralisation du SRAS-CoV-2 induits par le vaccin ont tous deux présenté des tendances similaires dans les deux groupes d'âge adultes (18 à 55 ans et 65 à 85 ans; N = 195). Chez les adultes, des réponses immunitaires maximales ont été observées au 28e jour, soit sept jours après la deuxième dose. Des anticorps de liaison et de neutralisation ont

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été induits par une dose de vaccin et stimulés par la seconde dose de vaccin. La réponse immunitaire déclenchée par la première dose représentait de 10 % à 20 % de la réponse immunitaire maximale. Jusqu'au 35e jour, les adultes plus âgés (de 65-85 ans) avaient une réponse immunitaire plus faible que les adultes moins âgés (de 18-55 ans). Après le pic du 28e jour, les réponses immunitaires ont diminué jusqu'au point d'évaluation final du 52e jour, soit 30 jours après la deuxième dose chez les adultes moins âgés, alors qu'aucune diminution n'a été observée chez les adultes plus âgés. Les réponses d'anticorps neutralisants du SRAS-CoV-2 un mois suivant la deuxième dose étaient comparables, sinon plus élevées, chez les adolescents de 12 à 15 ans par rapport aux jeunes adultes de 16 à 25 ans. À chaque point de temps testé et dans l'ensemble de tous les groupes d'âge inclus, les réponses immunitaires étaient plus élevées que chez les individus qui ont reçu le placebo.

Réponses immunitaires cellulaires

Les réponses immunitaires cellulaires ont été évaluées dans les groupes d'âge adulte (de 18 à 55 ans et de 65 à 85 ans). Les lymphocytes T CD4+ et CD8+ spécifiques au SRAS-CoV-2 ont été induits par le vaccin, comme le montre l'augmentation du pourcentage de ces cellules dans la population du 1er jour au 28e jour. Des augmentations ont été observées tant chez les adultes moins âgés (18-55 ans) que chez les adultes plus âgés (de 65-85 ans). La caractérisation de ces cellules indique une réponse immunitaire cellulaire biaisée de type Th-1. Les points intermédiaires n'ont pas été décrits.

Innocuité des vaccins et effets secondaires suivant l'immunisation

Les données probantes sur l'innocuité chez les participants de 16 ans et plus sont basées sur des analyses provisoires de 37 586 participants dont le suivi médian était de deux mois (plage : moins de 2 semaines à moins de 14 semaines) après la deuxième dose. Environ 19 000 participants ont fait l'objet d'au moins deux mois de suivi, dont environ 9 500 ont reçu le vaccin. Les participantes qui ont reçu par inadvertance le vaccin (n = 12) ou le placebo (n = 11) pendant leur grossesse font l'objet d'un suivi. Les données probantes sur l'innocuité chez les participants adolescents de 12 à 15 ans sont fondées sur des analyses intermédiaires de 2 260 participants. Approximativement 1 300 participants ont eu au moins deux (2) mois de suivi après la deuxième dose, dont 660 dans ce groupe vacciné.

Réactions locales

Chez les participants de 12 ans et plus ayant reçu le vaccin, la fréquence des réactions locales était similaire après la première dose et après la deuxième dose. La douleur au site d'injection était très courante (se produisant chez 86 % ou moins des adolescents de 12 à 15 ans après la première dose). La plupart des réactions locales chez les participants ayant reçu le vaccin étaient d'intensité légère ou modérée; des réactions sévères ont été déclarées par au plus 1 % des participants. Aucune réaction locale de Stade 4 n'a été déclarée. Dans tous les groupes d'âge adolescents et adultes, l'apparition médiane des réactions locales après l'une ou l'autre des doses était de zéro à deux jours après la vaccination, et leur durée médiane était d'un à trois jours.

Réactions systémiques

Les évènements systémiques étaient généralement plus fréquents et plus sévères chez les participants vaccinés par rapport à ceux qui ont reçu le placebo, et chez les adultes plus jeunes (16-55 ans) par rapport aux adultes plus âgés (de 56 ans et plus), la fréquence et la gravité augmentant avec le nombre de doses (la deuxième dose c. la première dose). La fatigue (de 34,1 % à 59,4 %), les maux de tête (de 25,2 % à 51,7 %) et les douleurs musculaires (de 13,9 %

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à 37,3 %) étaient très courants chez les adultes plus jeunes et plus âgés, respectivement après la première et la deuxième dose. La fièvre était courante après la première dose (3,7 % des 16 à 55 ans; 1,4 % des plus de 55 ans), mais elle était très courante après la deuxième dose (15,8 % des 16 à 55 ans; 10,9 % des plus de 55 ans). Les douleurs articulaires étaient très courantes ou courantes chez les adultes plus jeunes et plus âgés (de 11,0 % à 21,9 % des 16 à 55 ans; de 8,6 % à 18,9 % des plus de 55 ans). La diarrhée était très fréquente ou fréquente dans les deux groupes d'âge (10,0 à 11,0 % chez les 16 à 55 ans; 8,0 % chez les plus de 55 ans), mais les taux ont été comparables à ceux observés dans le groupe placebo et n'ont pas semblé varier entre la dose 1 et la dose 2.

Les événements systémiques étaient plus fréquents chez les adolescents comparativement aux adultes. Dans le groupe des adolescents, la fatigue (60,1 % à 66,0 %), les maux de tête (55,3 % à 64,5 %), les frissons (27,6 % à 41,5 %), les douleurs musculaires (24,1 % à 32,4 %) et la fièvre (10,1 % à 19,6 %) étaient très courants après la première dose et la deuxième dose, respectivement. Les douleurs articulaires étaient courantes après la première dose (9,7 %) et très courantes après la deuxième dose (15,8 %). Les vomissements (2,8 % à 2,6 %) et la diarrhée (8,0 % à 5,9 %) étaient courants après la première dose et la deuxième dose, respectivement.

Chez les adolescents et les adultes, le jour médian d'apparition de la plupart des évènements systémiques après l'une ou l'autre dose de vaccin était d'un à trois jours après la vaccination, avec une durée médiane d'un jour, à l'exception de la fatigue et des frissons avec des durées médianes d'un ou de deux jours. La majorité des évènements systémiques étaient de gravité légère ou modérée.

Dans l'ensemble, la fréquence de tout évènement sévère systémique après la première dose était de 0,9 % ou moins chez les personnes de 16 ans et plus. Après la deuxième dose, les évènements sévères systémiques ont affiché des fréquences de moins de 2 %, à l'exception de la fatigue (3,8 %) et des maux de tête (2,0 %). La proportion de participants qui ont fait une fièvre sévère (plus de 38,9 °C à 40,0 °C) a augmenté entre la première dose (0,2 %) et la deuxième dose (0,8 %). Une fièvre de Stade 4 (plus de 40,0 °C) a été signalée chez deux participants dans le groupe vacciné et chez deux participants dans le groupe témoin. Chez les adolescents de 12 à 15 ans, la fréquence des évènements systémiques sévères était de 3,5 % ou moins. Une fièvre de Stade 4 (40,4 °C) a été signalée chez un (1) participant du groupe vacciné.

Évènements indésirables graves ou sévères

Parmi les participants adultes de 16 ans et plus ayant reçu le vaccin, 1,1 % et 0,1 % d'entre eux ont ressenti au moins un ÉI sévère et un ÉI mettant la vie en danger, respectivement, par rapport à 0,7 % et à 0,1 % des participants du groupe placebo. Parmi les ÉI non sollicités non graves, il y avait un déséquilibre numérique de quatre cas de paralysie de Bell dans le groupe vacciné par rapport à aucun cas dans le groupe placébo. Ces cas de paralysie de Bell sont survenus 3, 9, 37 et 48 jours suivant la vaccination. Parmi les adolescents de 12 à 15 ans dans le groupe vacciné, 0,8 % et 0,1 % des participants ont ressenti au moins un ÉI sévère et un ÉI mettant la vie en danger, par rapport à 0,3 % et 0,1 % des participants au groupe placebo. Chez les adolescents, aucune différence cliniquement significative dans les ÉI n'a été observée selon l'âge, le sexe ou la race/l'ethnicité.

Les proportions des participants adultes de 16 ans et plus ayant déclaré au moins un ÉIG étaient similaires dans le groupe vacciné (0,5 %) et dans le groupe placebo (0,4 %), et étaient plus faibles chez les adolescents de 12 à 15 ans (0,4 % dans le groupe vacciné et 0,2 % dans le groupe placebo). Chez les adultes de 16 ans et plus, trois (3) des ÉIG dans le groupe vacciné et aucun dans le groupe placebo ont été évalués par le chercheur comme étant liés à l'intervention

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de l'étude : 1 ÉIG de blessure à l'épaule liée à l'administration du vaccin, 1 ÉIG d'arythmie ventriculaire et 1 ÉIG de lymphadénopathie. Aucun ÉIG signalé chez les adolescents de 12 à 15 ans n'a été évalué par le chercheur comme étant lié à l'intervention de l'étude. Aucune différence cliniquement significative dans les ÉIG n'a été observée selon l'âge, le sexe ou la race/l'ethnicité. Après l'une ou l'autre des doses de vaccin, aucun participant n'a déclaré de réaction allergique immédiate au vaccin.

Autres évènements indésirables graves

Lymphadénopathie

La lymphadénopathie n'était pas un ÉI sollicité sur demande. Parmi les participants de 16 ans et plus (n = 37 586) qui ont été suivis pendant une période de moins de 2 semaines à moins de 14 semaines après la deuxième dose, des ÉI de la lymphadénopathie ont été signalés chez 0,3 % (n = 64) des participants (0,5 % [n = 54] dans le groupe d'âge plus jeune et 0,1 % [n = 10] dans le groupe d'âge plus âgé) du groupe vacciné et chez 6 participants (0,0 %) du groupe placebo. La plupart des cas de lymphadénopathie ont été déclarés dans les deux à quatre jours suivant la vaccination. La durée moyenne de ces évènements était d'environ 10 jours, 11 évènements étant persistants à la date d'analyse des données. La lymphadénopathie liée à la vaccination chez les adolescents de 12 à 15 ans est survenue chez 0,6 % des vaccinés (0,8 % connexes et non connexes), et chez 0,1 % des receveurs de placebo (0,2 % connexes et non connexes). La plupart des cas ont été signalés dans les 2 à 10 jours suivant la vaccination et environ la moitié d'entre eux se sont résolus dans les 1 à 10 jours suivant la vaccination, d'autres évènements étant persistants à la date d'analyse des données.

Appendicite

Parmi les participants adultes de 16 ans et plus qui ont été suivis moins de 2 semaines à moins de 14 semaines après la deuxième dose, on comptait un total de 12 participants atteints d'appendicite, dont 8 dans le groupe vacciné. Six de ces huit cas sont survenus chez des adultes plus jeunes et deux chez des adultes plus âgés. Aucun des cas n'a été évalué comme étant lié au vaccin par les chercheurs. Le taux dans les deux groupes d'âge n'a pas été estimé plus élevé que prévu par rapport aux taux d'incidence de référence. Parmi les adolescents de 12 à 15 ans, un (1) participant du groupe vacciné et deux (2) participants du groupe placebo ont signalé des cas d'appendicite. Aucun de ces cas n'a été évalué par les chercheurs comme étant lié au vaccin.

Décès

Six décès ont été signalés chez les participants adultes (de 16 ans et plus) en date du 14 novembre 2020, date limite pour la réception des données aux fins de l'analyse intérimaire. Y sont compris deux participants du groupe vacciné et quatre du groupe placebo. Aucun de ces décès du groupe vacciné n'a été évalué comme étant lié au vaccin contre la COVID-19. Aucun décès n'a été signalé chez les adolescents de 12 à 15 ans.

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ANNEXE B : RÉSUMÉ DES DONNÉES PROBANTES DES ESSAIS CLINIQUES POUR LE VACCIN CONTRE LA COVID-19 DE MODERNA

Des essais pivots de Phases 1, 2 et 3 sont en cours pour le vaccin contre la COVID-19 de Moderna. Des données probantes sur l'efficacité, l'immunogénicité et l'innocuité sont disponibles pour les adultes de 18 ans et plus. Les études n'ont pas inclus de participants provenant d'établissements de soins de longue durée. La Phase 3 de l'essai a porté sur 30 413 participants randomisés (1:1) qui ont reçu soit le vaccin (2 doses de 100 mcg), soit un placebo. Les données présentées ci-dessous sont destinées à une analyse provisoire. Par conséquent, la durée du suivi n'est pas uniforme, mais était une durée médiane de deux mois après la deuxième dose (maximum de 14 semaines) pour tous les participants. Les données probantes tirées de la surveillance et des études post-commercialisation se trouvent dans le corps de la présente déclaration.

Efficacité

Complications sévères attribuables à la COVID-19
Il n'existe pas de données sur l'efficacité concernant les hospitalisations et les décès en particulier, mais il existe des données sur l'efficacité contre les complications sévères liées à la COVID-19, au sens donné à ce terme dans le protocole d'essai[140].

L'efficacité du vaccin contre la COVID-19 de Moderna pour protéger contre les cas sévères de COVID-19 survenant au moins 14 jours après la deuxième injection a été constatée chez 28 207 participants à l'étude (14 073 participants dans le groupe placebo et 14 134 participants dans le groupe du vaccin contre la COVID-19 de Moderna). Il y a eu 30 cas sévères confirmés de COVID-19 dans le groupe placebo contre 0 cas chez les participants ayant reçu le vaccin ARNm-1273, pour une efficacité vaccinale estimée à 100,0 % (IC à 95 % : non évaluable à 100,0 %).

COVID-19 symptomatique
Le principal résultat de l'efficacité de l'étude a porté sur l'efficacité du vaccin contre la COVID-19 de Moderna pour protéger contre la COVID-19 confirmée à partir de 14 jours après la deuxième dose chez les participants à l'étude âgés de 18 ans et plus sans preuve préalable d'une infection par le SRAS-CoV-2 au départ. Cette analyse a porté sur 28 207 participants à l'étude (14 134 participants dans le groupe placebo et 14 134 participants dans le groupe du vaccin contre la COVID-19 de Moderna), avec une durée médiane de suivi après avoir reçu la deuxième injection de 63 jours. Il y a eu 185 cas confirmés de COVID-19 [141]survenant au moins 14 jours après la deuxième injection chez les participants ayant reçu le placebo, contre 11 cas chez les participants ayant reçu le vaccin contre la COVID-19 de Moderna, pour une efficacité vaccinale estimée à 94,1 % (IC à 95 % : de 89,3 à 96,8 %).

Une analyse de sous-groupe du principal résultat intermédiaire de l'efficacité a été réalisée dans trois groupes d'âge : de 18 à 64 ans (10 551 participants dans le groupe placebo et 10 551 participants dans le groupe du vaccin contre la COVID-19 de Moderna), de 65 ans et plus (3 552 participants dans le groupe placebo et 3 583 participants dans le groupe du vaccin contre la COVID-19 de Moderna), et un autre sous-groupe de participants à l'étude de 75 ans et plus (688 participants dans le groupe placebo et 630 participants dans le groupe du vaccin contre la COVID-19 de Moderna).

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Chez les participants à l'étude âgés de 18 à 64 ans, il y a eu 156 cas confirmés de COVID-19 survenus au moins 14 jours après la deuxième injection chez les participants ayant reçu le placebo, contre 7 cas chez les participants ayant reçu le vaccin ARNm-1273, pour une efficacité vaccinale estimée de 95,6 % (IC à 95 % : de 90,6 à 97,9 %). Le taux d'incidence correspondant pour 1 000 personnes-années (durée totale du risque dans chaque groupe de traitement) était de 64,63 dans le groupe placebo et de 2,88 dans le groupe du vaccin contre la COVID-19 de Moderna. Chez les participants à l'étude de 65 ans et plus, il y a eu 29 cas confirmés de COVID-19 chez les participants ayant reçu le placebo contre 4 cas chez les participants ayant reçu le vaccin contre la COVID-19 de Moderna, ce qui correspond à une estimation ponctuelle un peu plus faible de l'efficacité du vaccin, soit 86,4 % (IC à 95 % : de 61,4 à 95,2 %). Le taux d'incidence correspondant pour 1 000 personnes-années était de 33,73 dans le groupe placebo et de 4,60 dans le groupe du vaccin contre la COVID-19 de Moderna. Dans le sous-groupe de participants à l'étude de 75 ans et plus, il y a eu 7 cas confirmés de COVID-19 parmi les participants ayant reçu le placebo contre 0 cas parmi les participants ayant reçu le vaccin contre la COVID-19 de Moderna, pour une efficacité correspondante du vaccin de 100,0 % (IC à 95 % : non évaluable à 100,0 %), mais cela doit être interprété avec prudence, car peu d'évènements ont été relevés dans ce groupe d'âge.

L'efficacité du vaccin contre la COVID-19 de Moderna pour protéger contre les cas confirmés de COVID-19 survenant au moins 14 jours après la deuxième injection a également été évaluée chez les participants les plus exposés au risque de complications sévères liées à la COVID-19. Chez les participants à l'étude âgés de 18 à 64 ans et à risque de complications sévères liées à la COVID-19 (2 118 participants dans le groupe placebo et 2 155 participants dans le groupe du vaccin contre la COVID-19 de Moderna), il y avait 35 cas confirmés de COVID-19 dans le groupe placebo, contre deux (2) cas parmi les participants ayant reçu le vaccin contre la COVID-19 de Moderna, pour une efficacité vaccinale estimée à 94,4 % (IC à 95 % : de 76,9 à 98,7 %). Chez les participants à l'étude âgés de 18 à 64 ans, mais sans risque de complications sévères liées à la COVID-19 (8 403 participants dans le groupe placebo et 8 396 participants dans le groupe du vaccin contre la COVID-19 de Moderna), l'efficacité du vaccin estimée était de 95,9 % (IC à 95 % : de 90,0 à 98,3 %) sur la base de 121 cas confirmés de COVID-19 dans le groupe placebo et de 5 cas parmi les participants ayant reçu le vaccin contre la COVID-19 de Moderna. Les estimations de l'efficacité du vaccin ont également été calculées pour certaines pathologies comorbides individuelles; toutefois, au 7 novembre 2020, le nombre d'évènements relevés dans ces sous-groupes (n = 0 à 11) était trop faible pour permettre une analyse significative.

Une analyse secondaire de l'efficacité du vaccin pour protéger contre la première apparition de COVID-19 confirmée commençant 14 jours après la deuxième dose, indépendamment d'une infection antérieure par le SRAS-CoV-2, telle que déterminée par le titre sérologique, a porté sur l'ensemble de l'analyse (participants à l'étude assignés au hasard ayant reçu au moins une injection). Il y avait 30 351 participants à l'étude âgés de 18 ans ou plus (15 170 participants dans le groupe placebo et 15 181 participants dans le groupe du vaccin contre la COVID-19 de Moderna). Il y a eu 187 cas confirmés de COVID-19 chez les personnes ayant reçu le placebo, contre 12 cas chez les personnes ayant reçu le vaccin contre la COVID-19 de Moderna, pour une efficacité vaccinale estimée à 93,6 % (IC à 95 % : de 88,6 à 96,5 %). Cependant, une petite proportion des participants à l'étude (n = 679/29 148; 2,3 %) avaient un état sérologique positif pour le SRAS-CoV-2 au départ.

Chez les participants qui n'avaient reçu qu'une dose du vaccin au moment de l'analyse des données (groupe placebo : n = 1 079; groupe du vaccin : n = 996), l'efficacité du vaccin se chiffrait à 80,2 % (IC à 95 % : 55,2 à 92,5 %). Lorsqu'on limite l'analyse aux 14 jours ou plus suivant l'administration de la première dose, le taux d'efficacité augmente à 92,1 % (IC à 95 % : 68,8 à

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99,1 %). Toutefois, il y a des données limitées sur l'efficacité d'une seule dose, plus de 28 jours après la vaccination.

Tableau 9. Efficacité du vaccin de Moderna contre la première apparition de la COVID-19 symptomatique après la première dose [a]

Période d'intérêt	Évènements dans le groupe vacciné (N = 996)	Évènements dans le groupe placebo (N = 1 079)	Estimation de l'efficacité du vaccin (IC à 95 %)
Après la première dose	7	39	80,2 % (55,2 à 92,5 %)
Plus de 14 jours après la première dose	2	28	92,1 % (68,8 à 99,1 %)

[a]Dans la population en intention de traiter modifiée, composée de participants à l'étude randomisée qui n'avaient reçu qu'une seule dose de l'intervention qui leur avait été attribuée (vaccin ou placebo) au moment de l'analyse.

Infection asymptomatique et transmission

Des écouvillonnages du nasopharynx pour le virus SRAS-CoV-2 ont été collectés chez tous les participants à des intervalles déterminés avant la première dose et avant la deuxième dose. Quatorze participants du groupe vacciné qui étaient séronégatifs avant l'administration de la première dose présentaient une infection asymptomatique au second point temporel, comparativement à 38 participants dans le groupe placebo. Il n'existe aucune donnée officielle en matière d'efficacité; toutefois, l'évaluation à cet égard est en cours.

Immunogénicité

Réponses immunitaires humorales

Les anticorps qui se lient à la protéine de spicule ont été induits chez les participants ayant reçu le vaccin au jour 15 (15 jours après la première dose) et ils atteignent leur niveau maximal au jour 43 (15 jours après la deuxième dose). Les réponses anticorps de liaison maximales se rapprochent des niveaux des échantillons de sérums en phase de convalescence ayant la plus grande affinité. Les anticorps de liaison ont atteint des niveaux élevés au jour 36 (7 jours après la deuxième dose) et ont persisté quoique diminué jusqu'au jour 119 (90 jours après la deuxième dose), dernier jour pour lequel des données sont disponibles.

Les anticorps de liaison induits par une dose du vaccin (c'est-à-dire au jour 29) représentaient de 10 à 20 % des réponses élevées observées le jour 36. On ignore comment les réponses anticorps de liaison changent avec le temps. Les réponses anticorps de liaison jusqu'au jour 36 semblent être à peu près équivalentes d'un groupe d'âge à l'autre. Les données pourraient indiquer une durabilité des anticorps de liaison en fonction de l'âge. Les réponses anticorps pour les groupes d'âge de 70 ans et moins ont diminué plus lentement que celles pour les groupes d'âge supérieurs à 70 ans.

Les anticorps neutralisants n'ont été induits au niveau des sérums en phase de convalescence qu'au 36e jour, soit sept jours après la deuxième dose pour tous les groupes d'âge. Les réponses anticorps neutralisants jusqu'au jour 36 semblent être à peu près équivalentes d'un groupe d'âge à l'autre. Les réponses anticorps neutralisants au jour 119 représentent une plus grande proportion du maximum au jour 43, par rapport aux réponses des anticorps de liaison. Cela peut indiquer une durabilité accrue des réponses anticorps neutralisants par rapport aux réponses anticorps de liaison. Ces données sur les anticorps neutralisants peuvent également indiquer une

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durabilité des anticorps neutralisants en fonction de l'âge, car les réponses anticorps au jour 119 de chaque cohorte étaient inversement proportionnelles à l'âge de la cohorte.

Les données d'immunogénicité d'un essai de Phase 1 portant sur le vaccin contre la COVID-19 de Moderna chez un nombre restreint de sujets (n = 33) révèlent une persistance d'anticorps s'étendant à 6 mois[142].

Réponses immunitaires à médiation cellulaire
Les lymphocytes T CD4+ et CD8+ propres au SRAS-CoV-2 ont été induits par le vaccin. L'induction maximale des lymphocytes T CD4+ et CD8+ a été observée au jour 43, 14 jours après la dose 2. Le pourcentage de lymphocytes T CD8+ était plus faible pour tous les groupes d'âge que celui des lymphocytes T CD4+. En comparant le pourcentage de cellules qui expriment Th-1 (IFN gamma, IL-2, TNF) par rapport à Th-2 (IL-4 et IL-13), il a été démontré que ce vaccin induit principalement une réponse immunitaire à médiation cellulaire de type Th1.

Innocuité du vaccin et effets secondaires suivant l'immunisation

Les données probantes sur l'innocuité sont basées sur des analyses intermédiaires de 30 351 participants avec une durée de suivi médiane de 63 jours après la dose 2 (92 jours après la dose 1).
23 276 participants ont fait l'objet d'au moins un mois de suivi après la dose 2 (12 021 personnes ont reçu le vaccin) et 7 667 personnes ont fait l'objet d'au moins 2 mois de suivi après la dose 2 (3 894 personnes ont reçu le vaccin)[141]. Les participantes qui ont reçu par inadvertance le vaccin (n = 6) ou le placebo (n = 7) pendant leur grossesse font l'objet d'un suivi.

Réactions locales sollicitées
Chez les participants ayant reçu le vaccin, la fréquence des réactions locales a augmenté entre la dose 1 et la dose 2. La douleur au site d'injection était très courante (83,7 % des participants ayant reçu le vaccin après la dose 1 et 88,2 % des participants ayant reçu le vaccin après la dose 2). Les rougeurs étaient courantes (2,8 à 8,6 %) et le gonflement était courant à très courant (6,1 à 12,2 %). Des réactions de Stade 3 (sévères) ont été signalées respectivement par 3,5 % et 7,0 % des participants ayant reçu le vaccin après la dose 1 et la dose 2[141]. Aucune réaction locale de Stade 4 n'a été déclarée. La majorité des réactions locales après l'une ou l'autre dose sont survenues dans les 1 à 2 jours suivant la vaccination et ont eu une durée médiane de 1 à 3 jours. Des réactions tardives au site d'injection (c'est-à-dire apparaissant au jour 8 ou après) ont été notées chez 0,8 % des participants après la première dose et chez 0,2 % des participants après la deuxième dose. Les réactions étaient caractérisées par un érythème, une induration et une sensibilité, et elles ont disparu en 4 à 5 jours.

Un gonflement axillaire localisé et une sensibilité constituaient des effets sollicités sur demande et sont apparus chez moins de 5 % des participants ayant reçu le placebo après une dose quelconque, et chez 10,2 % et 14,2 % des participants ayant reçu le vaccin après, respectivement, la dose 1 et la dose 2. Parmi les participants ayant reçu le vaccin, l'incidence du gonflement axillaire et de la sensibilité sévères (Stade 3) a augmenté entre la dose 1 et la dose 2 (de 0,3 à 0,5 %), tandis que dans le groupe placebo, elle a diminué entre la dose 1 et la dose 2 (de 0,2 à 0,1 %)[127].

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Réactions systémiques sollicitées

Les évènements systémiques étaient généralement plus fréquents et plus graves chez les personnes ayant reçu le vaccin que chez celles ayant reçu le placebo, la fréquence et la gravité augmentant avec le nombre de doses (dose 1 par rapport à la dose 2). Chez les participants ayant reçu le vaccin, la fatigue (de 37,2 à 65,3 %), les maux de tête (de 32,6 à 58,6 %), les douleurs musculaires (de 22,7 à 58,0 %) et l'arthralgie (de 16,6 à 42,8 %) étaient très courants dans tous les groupes d'âge et, respectivement, après la dose 1 et la dose 2. Les frissons et les nausées/vomissements étaient très fréquents ou fréquents (respectivement de 8,3 à 44,2 % et de 8,3 à 19,0 %). La fièvre était peu courante après la première dose (0,8 %), mais très courante après la deuxième dose (15,5 %).

Des réactions de Stade 3 ont été signalées respectivement par 2,9 % et 15,7 % des participants ayant reçu le vaccin après la dose 1 et la dose 2[141]. Après la dose 2, la fièvre de Stade 3 (1,3 %), les maux de tête (4,3 %), la fatigue (9,4 %), la myalgie (8,7 %), l'arthralgie (5,1 %) et les frissons (1,3 %) étaient courants. La proportion des vaccinés qui ont ressenti de la fièvre de Stade 3 (plus de 38,9 °C à 40,0 °C) a augmenté entre la première dose (moins de 0,1 %; n = 11) et la deuxième dose (1,3 %; n = 202). Parmi les participants ayant reçu le placebo, seuls 2,7 % ont déclaré des ÉI de Stade 3 après l'une ou l'autre dose.

L'incidence des évènements de Stade 4 était moins de 0,1 % après les deux doses chez les participants ayant reçu le vaccin (de 6 à 12 évènements) et le placebo (de 2 à 4 évènements). Une fièvre de Stade 4 (plus de 40,0 °C) a été signalée chez 4 participants ayant reçu le placebo et 4 participants ayant reçu le vaccin après la dose 1, et 2 participants ayant reçu le placebo et 12 participants ayant reçu le vaccin après la dose 2. La majorité des réactions systémiques après l'une ou l'autre dose sont survenues dans les 1 à 2 jours suivant la vaccination et ont eu une durée médiane de 1 à 2 jours.

Évènements indésirables sévères ou graves non sollicités

Au cours des 28 premiers jours suivant l'administration de chaque dose, 1,5 % et 0,5 % des participants du groupe du vaccin (dose 1 et dose 2, respectivement) ont signalé des ÉIG et des ÉI sévères non sollicités, contre 1,3 % et 0,6 % des participants du groupe placebo, Il n'y avait pas eu d'effet apparent de l'âge sur l'incidence relative des ÉIG dans le groupe du vaccin out le groupe placebo. Il y a eu trois cas de paralysie de Bell dans le groupe vacciné qui se sont produits 22, 29 et 32 jours après la deuxième dose et un cas dans le groupe placébo qui s'est produit 17 jours après l'injection. Un ca de paralysie de Bell dans le groupe vacciné a été considéré comme un ÉIG (femme de 67 ans diabétique hospitalisée pour un AVC en raison d'une nouvelle paralysie faciale 32 jours après la vaccination).

Trois des ÉIG chez les participants ayant reçu le vaccin ont été évalués par les chercheurs comme étant liés à l'intervention de l'étude : deux cas de gonflement facial et un cas de nausées et de vomissements accompagnés de maux de tête et de fièvre.

Les chercheurs de l'étude ont considéré que quatre autres cas d'ÉIG chez les participants vaccinés et cinq autres chez les participants ayant reçu un placebo étaient liés à l'intervention de l'étude[141]. Parmi les ÉIG considérés comme liés au vaccin de Moderna, deux cas de maladies auto-immunes ont été signalés : une polyarthrite rhumatoïde chez un participant souffrant d'hypothyroïdie, non résolue au moment du rapport, et un dysfonctionnement au tonome chez un participant souffrant d'hypothyroïdie, également non résolu au moment du rapport. Dans le

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groupe placebo, un participant (souffrant de douleurs dorsales chroniques) a développé une pseudo-polyarthrite rhyzomélique, en voie de résorption.

Aucune différence cliniquement significative dans les ÉIG n'a été observée selon l'âge. Le sexe et la race/l'ethnicité n'ont pas été évalués. Après l'une ou l'autre des doses de vaccin, aucun participant à l'étude de Phase 3 n'a déclaré de réaction allergique immédiate au vaccin.

Autres évènements indésirables graves

Œdème facial

Deux participantes ayant déjà reçu des injections de produit de remplissage dermique dans les joues ont présenté un œdème facial de 1 à 2 jours après l'administration du vaccin. Elles ont été traitées, et l'œdème a disparu au bout d'environ cinq jours. Une troisième participante ayant déjà reçu des injections de produits de remplissage dermique dans les lèvres a présenté un œdème de Quincke au niveau des lèvres deux jours après la vaccination, qui a été qualifié d'important sur le plan médical, mais pas considéré comme un ÉIG. La durée de ce troisième événement et la façon dont il a été géré n'ont pas été précisées.

Décès

Au total, treize décès ont été signalés, six dans le groupe du vaccin et sept dans le groupe placebo. Aucun de ces décès n'a été évalué comme étant lié à une quelconque intervention de l'étude ou à la COVID-19.

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ANNEXE C : RÉSUMÉ DES DONNÉES PROBANTES DES ESSAIS CLINIQUES POUR LE VACCIN CONTRE LA COVID-19 D'ASTRAZENECA

Les résultats de quatre essais cliniques (deux Phases 1/2, une Phase 2/3 et une Phase 3) étaient disponibles au moment de l'autorisation du vaccin contre la COVID-19 d'AstraZeneca. Les résultats d'un essai de Phase 3 en cours aux États-Unis n'étaient pas disponibles au moment de la rédaction du présent document. Des données probantes sur l'efficacité potentielle, l'immunogénicité et l'innocuité sont disponibles pour les adultes de 18 ans et plus. L'essai de Phase 2/3 (COV002) et l'essai de Phase 3 (COV003) ont permis d'évaluer l'efficacité potentielle, l'innocuité et l'immunogénicité du vaccin. L'essai de la Phase 2/3 était basé au Royaume-Uni (R.-U.), tandis que l'essai de la Phase 3 était basé au Brésil. Ces deux études ont subi une série de modifications de protocole et de défis logistiques pendant la conduite des essais, ce qui a entraîné des changements importants dans la méthodologie des essais. Il y a eu des changements d'un schéma vaccinal à dose unique à un schéma à deux doses, le lancement d'un schéma vaccinal à faible dose/dose standard (LD/SD) [COV002 uniquement] et à dose standard/dose standard (SD/SD), et le recrutement de participants à l'étude progressivement plus âgés (56 à 69 ans, puis 70 ans et plus), après l'accent initial mis sur les adultes de 18 à 55 ans. Dans le schéma de vaccination SD/SD, les participants à l'étude ont été randomisés (1:1) pour recevoir soit le vaccin contre la COVID-19 d'AstraZeneca, AZD1222 (5×10^{10} particules virales par dose de 0,5 ml), soit une injection témoin. Les participants randomisés dans le groupe de contrôle ont reçu deux doses de vaccin méningococcique quadrivalent (MenACWY) [COV002], ou le vaccin MenACWY pour la dose 1 et un placebo pour la dose 2 (COV003).

Il y a eu des différences significatives dans les caractéristiques de base des participants aux essais de la Phase 2/3 et de la Phase 3. En outre, les essais cliniques ont donné la priorité au recrutement de professionnels de la santé et d'autres adultes présentant un fort potentiel d'exposition au SRAS-CoV-2, notamment les travailleurs des services de santé et des services sociaux.

Les données probantes provenant des essais sur le vaccin contre la COVID-19 d'AstraZeneca ont été publiées[143]. Les données probantes tirées de la surveillance et des études post-commercialisation se trouvent dans le corps de la présente déclaration.

Efficacité potentielle

Les estimations de l'efficacité potentielle du vaccin contre la COVID-19 d'AstraZeneca (AZD1222) proviennent des essais de Phase 2/3 et de Phase 3. À la date limite de réception des données, le 4 novembre 2020, la population de l'analyse primaire des résultats (participants à l'étude ayant reçu les vaccins selon le schéma vaccinal LD/SD ou SD/SD) comptait 11 636 participants séronégatifs au départ (5 807 vaccinés et 5 829 témoins). De cette population, 8 895 participants (4 440 vaccinés et 4 455 témoins) ont reçu les vaccins selon le schéma vaccinal SD/SD. À la date limite de réception des données, le 7 décembre 2020, 12 158 participants à l'étude (6 085 personnes vaccinés et 6 073 témoins) avaient reçu le schéma vaccinal SD/SD. Sauf indication contraire, toutes les données présentées dans ce résumé sont fondées sur le schéma vaccinal SD/SD et sur une date limite de réception des données du 7 décembre 2020.

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COVID-19 symptomatique

Le principal résultat d'efficacité potentielle évalué dans les deux essais était la prévention de la première apparition de COVID-19 confirmée 15 jours ou plus après la deuxième dose. Il reposait sur des évaluations des cas par un Comité d'adjudication, sans tenir compte de l'affectation du groupe de participants, et analysé dans la population du schéma combiné LD/SD et SD/SD. L'évaluation dans le sous-groupe qui n'a reçu que le SD/SD était une analyse secondaire prédéfinie dans l'essai clinique. La COVID-19 symptomatique a été définie comme ayant au moins un des symptômes suivants (fièvre objective de 37,8 °C ou plus, toux, essoufflement et anosmie ou agueusie) ET un écouvillon positif pour le SRAS-CoV-2 par RT-PCR ET confirmé par un Comité d'adjudication.

Selon les données du 7 décembre 2020, 12 158 participants âgés de 18 ans ou plus, sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion (6 085 personnes vaccinées et 6 073 témoins), ont été inclus dans l'analyse du schéma SD/SD. L'efficacité potentielle estimée du vaccin contre les cas confirmés de COVID-19 survenant 15 jours ou plus après la deuxième dose chez les participants à l'étude ayant reçu le schéma vaccinal SD/SD était de 62,5 % (IC à 95 % : 50,7 à 71,4 %), sur la base de l'identification de 71/6 085 (1,2 %) cas chez les personnes vaccinées et de 186/6 073 (3,1 %) cas chez les témoins. L'efficacité potentielle estimée du vaccin selon l'âge était de 63,1 % (51,1 à 72,1 %) chez les participants à l'étude âgés de 18 à 64 ans et de 50,7 % (-65,8 à 85,4 %) chez les participants âgés de 65 ans ou plus. Une analyse du sous-groupe ponctuelle effectuée dans le but d'examiner l'effet confondant potentiel de l'âge et de l'intervalle entre les doses du vaccin sur les estimations de l'efficacité vaccinale pendant l'essai clinique COV002 (R.-U.) a généré une estimation sur l'efficacité vaccinale chez les participants à l'étude âgés de 18 à 55 ans qui ont reçu les deux doses du schéma SD/SD. Selon les données provisoires à la date limite du 4 novembre 2020, l'analyse du sous-groupe a trouvé une efficacité vaccinale de 59,3 % (95 % CI : 25,1 à 77,9 %) dans ce groupe d'âge. Cette analyse a porté sur les participants à l'étude, quel que soit l'intervalle entre les doses.

<u>COVID-19 symptomatique par intervalle</u>

Au 7 décembre 2020, la majorité des participants aux essais cliniques COV002 (R.-U.) et COV003 (Brésil) avaient reçu les deux doses du schéma SD/SD dans un intervalle de 4 à 8 semaines (R.-U. : 45,6 %, Brésil : 87,2 %) ou de 9 à 12 semaines (R.-U. : 34,4 %, Brésil : 10,5 %). Un participant environ sur cinq à l'essai clinique britannique (18,9 %) a reçu le schéma SD/SD avec un intervalle de plus de 12 semaines entre les doses de vaccin. Dans l'essai brésilien, cela concernait moins d'un participant sur 50 (1,8 %). Une très faible proportion des participants à l'étude a reçu le schéma SD/SD avec un intervalle de moins de 4 semaines entre les doses (R.-U. : 1 %, Brésil : 0,4 %).

Une analyse exploratoire a examiné l'effet potentiel de l'intervalle entre l'administration de la première et de la deuxième dose de vaccin sur l'efficacité potentielle du vaccin chez les participants à l'étude recevant le schéma vaccinal SD/SD. Le Tableau 10 résume les estimations de l'efficacité potentielle du vaccin contre les cas confirmés de la COVID-19 survenant 15 jours ou plus après la deuxième dose, par intervalle de dosage. Il semblerait que l'estimation ponctuelle de l'efficacité potentielle d'un vaccin augmente avec l'intervalle entre la première et la deuxième dose de vaccin. Toutefois, il est important de noter que les intervalles de confiance autour de ces estimations ponctuelles se chevauchent.

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Tableau 10. Estimations de l'efficacité potentielle du vaccin contre la première apparition de COVID-19 confirmée à partir de 15 jours après la deuxième dose, par intervalle de dosage (ensemble d'efficacité de base SD/SD séronégatif[a])

Intervalle de dosage	Évènement dans le groupe vacciné (AZD1222) n/N (%)	Évènements dans le groupe témoin (MenACWY) n/N (%)	Efficacité potentielle du vaccin (IC à 95 %)
4 à 12 semaines	67/5 473 (1,2)	162/5 422 (3)	59,6 % (46,4 à 69,6 %)
4 à 8 semaines	52/4 188 (1,2)	113/4 098 (2,8)	55,7 % (38,5 à 68,1 %)
9 à 12 semaines	15/1 285 (1,2)	49/1 324 (3,7)	69 % (44,8 à 82,6 %)
Plus de 12 semaines	4/571 (0,7)	22/599 (3,7)	81,6 % (47 à 93,6 %)

[a]Participants sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion; tous les bénéficiaires du vaccin SD/SD (ou les témoins respectifs).

Dans une analyse de sous-groupe chez les participants à l'étude qui ont reçu le schéma vaccinal SD/SD, l'efficacité potentielle du vaccin contre les cas confirmés de COVID-19 survenant 15 jours ou plus après la deuxième dose a été estimée par intervalle de dosage et par groupe d'âge. Ces analyses ponctuelles du sous-groupe ont été effectuées chez les participants âgés de 18 à 55 ans pendant l'essai clinique COV002 (R.-U.) et chez tous les participants qui ont reçu les deux doses du schéma SD/SD (des COV002 et COV003), répartis en deux groupes de 18 à 64 ans et de 65 ans et plus.

L'analyse ponctuelle du sous-groupe effectuée pour examiner l'effet confondant potentiel de l'âge et de l'intervalle entre les doses sur les estimations de l'efficacité vaccinale pendant l'essai clinique COV002 (R.-U.) a généré une estimation de l'efficacité vaccinale chez les participants à l'étude âgés de 18 à 55 ans qui ont reçu le schéma SD/SD à un intervalle de plus de 8 semaines entre les doses. Basée sur les données provisoires à la date limite du 4 novembre 2020, cette analyse du sous-groupe a généré une estimation de l'efficacité vaccinale de 65,6 % (95 % CI : 24,5 à 84,4 %). Dans l'ensemble de données actualisé au 7 décembre 2020, on comptait 1 375 participants à l'étude de 65 ans ou plus (699 dans le groupe vacciné et 676 dans le groupe témoin). Les estimations de l'efficacité potentielle pour les participants de 65 ans ou plus pour l'intervalle de dosage global de 4 à 12 semaines et celui de 4 à 8 semaines ont des intervalles de confiance larges qui incluent zéro. Les estimations de l'efficacité potentielle du vaccin n'ont pas pu être calculées pour les participants de 65 ans et plus pour les intervalles de dosage de 9 à 12 semaines et de plus de 12 semaines, en raison du manque de participants à l'étude plus âgés qui ont reçu le schéma SD/SD pendant ces intervalles de dosage (Tableau 11).

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Tableau 11. Estimations de l'efficacité potentielle du vaccin contre la première apparition de COVID-19 confirmée à partir de 15 jours après la deuxième dose, par intervalle de dosage et groupe d'âge (ensemble d'efficacité potentielle de base SD/SD séronégatif[a])

Intervalle de dosage et groupe d'âge	Évènement dans le groupe vacciné (AZD1222) n/N (%)	Évènements dans le groupe témoin (MenACWY) n/N (%)	Efficacité potentielle du vaccin (IC à 95 %)
4 à 12 semaines			
18 à 64 ans	63/4 790 (1,2)	156/4 760 (3)	60,5 % (47,1 à 70,5 %)
65 ans et plus	4/683 (0,6)	6/662 (0,9)	43,2 % (-99,3 à 83,8 %)
4 à 8 semaines			
18 à 64 ans	48/3 506 (1,4)	107/3 439 (3,1)	56,6 % (39,1 à 69,1 %)
65 ans et plus	4/682 (0,6)	6/659 (0,9)	43,4% (-98,5 à 83,9 %)
9 à 12 semaines			
18 à 64 ans	15/1 284 (1,2)	49/1 321 (3,7)	69 % (44,8 à 82,6 %)
65 ans et plus	0/1 (0)	0/3 (0)	Pas d'estimation
Plus de 12 semaines			
18 à 64 ans	4/571 (0,7)	22/599 (3,7)	81,6 % (47 à 93,6 %)
65 ans et plus	0/0 (0)	0/0 (0)	Pas d'estimation

[a] Participants sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion; tous les bénéficiaires du vaccin SD/SD (ou les témoins respectifs).

COVID-19 symptomatique par la présence d'une comorbidité

L'efficacité potentielle a également été évaluée en fonction de l'existence d'une comorbidité, définie comme la présence d'une ou plusieurs des affections médicales suivantes, légères à modérées et contrôlées au départ : maladie cardiovasculaire, maladie respiratoire, diabète ou obésité (IMC de 30 kg/m^2 ou plus), selon les données à la date limite du 4 novembre 2020. Pour cette analyse exploratoire, nous avons inclus les participants à l'étude qui étaient séronégatifs pour le SRAS-CoV-2 au départ et qui ont reçu le schéma SD/SD. L'efficacité potentielle estimée du vaccin contre les cas confirmés de COVID-19 survenant 15 jours ou plus après la deuxième dose chez les participants à l'étude sans comorbidité était de 58 % (IC à 95 % : 25,8 à 76,2 %), sur la base de 17/2 825 (0,6 %) cas décelés dans le groupe vacciné contre 39/2 774 (1,4 %) cas dans le groupe témoin. L'estimation correspondante de l'efficacité potentielle du vaccin chez les participants à l'étude présentant des comorbidités était de 67,1 % (IC à 95 % : 33,2 à 83,8 %), sur la base de l'identification de 10/1 611 (0,6 %) cas dans le groupe vacciné contre 32/1 670 (1,9 %) cas dans le groupe témoin.

COVID-19 symptomatique après une dose

L'efficacité potentielle à divers moments après une dose du vaccin contre la COVID-19 d'AstraZeneca a été évaluée dans le cadre d'une analyse secondaire/exploratoire basée sur les données à la date limite de l'analyse intermédiaire du 4 novembre 2020 (Tableau 12). L'analyse a porté sur des participants à l'étude qui étaient séronégatifs pour le SRAS-CoV-2 au départ et qui ont reçu le vaccin SD comme première dose de vaccin. La durée médiane du suivi était de 115 jours (fourchette : 41 à 149 jours) après la première dose. Il faut noter qu'environ 80 % des participants à l'étude dans le groupe vacciné ont reçu la deuxième dose du vaccin; par conséquent, plusieurs estimations de l'efficacité potentielle du vaccin ne sont pas uniquement attribuables à la seule dose de vaccin SD.

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Tableau 12. Estimations de l'efficacité potentielle du vaccin contre la première apparition de COVID-19 confirmée à partir de la première dose (ensemble d'efficacité potentielle de base SD/SD séronégatif[a])

Période d'intérêt	Évènements dans le groupe vacciné (AZD1222)	Évènements dans le groupe témoin (MenACWY)	Estimation de l'efficacité potentielle du vaccin (IC à 95 %)
Après la première dose	92 (N = 8 008)	185 (N = 8 013)	50,5 % (36,5 à 61,5 %)
22 jours ou plus après la première dose	51 (N = 6 307)	141 (N = 6 297)	64,1 % (50,5 à 73,9 %)
22 jours ou plus après la première dose mais avant la deuxième	15 (N = 6 310)	52 (N = 6 296)	71,3 % (49 à 83,8 %)

[a] Participants sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion; tous les bénéficiaires du vaccin SD/SD (ou les témoins respectifs).

Complications sévères de la COVID-19

Formes sévères de la COVID-19

Les formes sévères de la COVID-19, c'est-à-dire les participants à l'étude qui répondaient à la définition de cas confirmé de COVID-19 et qui ont reçu un score de gravité de 6 ou plus sur l'échelle de progression clinique de l'OMS (p. ex., gravité clinique nécessitant une hospitalisation, et pouvant inclure l'intubation et la ventilation mécanique, et le décès), ont été évaluées en tant qu'analyse secondaire de l'efficacité potentielle du vaccin. L'analyse a porté sur les participants à l'étude qui avaient été suivis pendant 15 jours ou plus après la deuxième dose, qui étaient séronégatifs pour le SRAS-CoV-2 au départ et qui ont reçu les deux doses du schéma SD/SD. Au 7 décembre 2020, 6 085 personnes avaient participé à l'étude dans le groupe vacciné et 6 073 personnes avaient participé dans le groupe témoin. Un cas sévère de COVID-19 a été décelé chez un participant du groupe témoin qui a reçu l'intervention témoin dans l'intervalle de 4 à 12 semaines. Ce participant a également dû être admis à l'USI et est finalement décédé. Un autre cas sévère s'est produit plus de 21 jours après la première dose et à 14 jours ou moins après la deuxième dose chez un participant à l'étude dans le groupe témoin.

Hospitalisations

L'efficacité potentielle du vaccin contre les hospitalisations associées à la COVID-19 a été évaluée à plusieurs moments (Tableau 13). L'évaluation a porté sur les participants à l'étude qui étaient séronégatifs pour le SRAS-CoV-2 au départ et qui ont reçu les deux doses du schéma SD/SD. Après la deuxième dose (durée médiane du suivi : 36 jours, intervalle : 1 à 79 jours, basée sur les données à la date limite du 4 novembre 2020), on a recensé 7 hospitalisations attribuables à la COVID-19 chez les participants à l'étude qui ont reçu le schéma SD/SD dans l'intervalle de 4 à 12 semaines, toutes chez les participants du groupe témoin. Il n'y a eu aucune hospitalisation dans le groupe vacciné 22 jours ou plus après la première dose; toutefois, deux cas d'hospitalisation attribuables à la COVID-19 ont été constatés dans le groupe vacciné et 16 dans le groupe témoin 15 jours ou plus après la première dose, ce qui donne une estimation d'efficacité potentielle du vaccin de 87,6 % (IC à 95 % : 46 à 97,2 %). Les deux hospitalisations dans le groupe vacciné ont eu lieu 1 et 10 jours après la vaccination (suivi médian : 115 jours, fourchette : 41 à 149).

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Tableau 13. Estimations de l'efficacité potentielle du vaccin contre l'hospitalisation, par intervalle de dosage (ensemble d'efficacité potentielle de base SD/SD séronégatif[a])

Période d'intérêt	Évènement dans le groupe vacciné (AZD1222) n/N (%)	Évènements dans le groupe témoin (MenACWY) n/N (%)	Efficacité potentielle du vaccin (IC à 95 %)
22 jours ou plus après la première dose[b]	0/6 307 (0)	9/6 297 (0,1)	100 % (IC à 95 % : 49,6 à non évaluable)
15 jours ou plus après la deuxième dose[c]	0/6 085 (0)	7/6 073 (0,1)	S.O.

[a] Participants sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion; tous les bénéficiaires du vaccin SD/SD (ou les témoins respectifs).
[b] Basé sur les données à la date limite du 4 novembre 2020
[c] Basé sur les données à la date limite du 7 décembre 2020

Décès

À la date limite de mise à jour des données, le 7 décembre 2020, un seul décès attribuable à la COVID-19 a été constaté chez un participant à l'étude du schéma SD/SD dans le groupe témoin.

Infection asymptomatique et transmission

Il s'agit d'une analyse exploratoire menée uniquement dans le cadre de l'essai clinique COV002 (R.-U.). Dans le cadre du protocole de l'étude, une semaine après la réception de la première dose, on a demandé aux participants à l'étude de fournir chaque semaine des écouvillons nasaux ou pharyngés auto-administrés pour le test RT-PCR. Toutefois, la présence ou l'absence de symptômes au moment du prélèvement de l'échantillon n'a pas été systématiquement relevée. Une infection asymptomatique a été définie comme un participant à l'étude dont l'infection par le SRAS-CoV-2 a été confirmée par l'analyse virologique d'un prélèvement effectué à l'aide d'un écouvillon, et qui n'a signalé aucun symptôme défini par l'essai clinique de la COVID-19 confirmée. Les participants à l'étude dont l'infection par le SRAS-CoV-2 a été confirmée par une analyse virologique, mais qui n'ont pas signalé s'ils présentaient ou non des symptômes, ont été classés dans la catégorie « symptômes inconnus ».

Tableau 14. Estimations de l'efficacité potentielle du vaccin contre l'infection asymptomatique, par intervalle de dosage (ensemble d'efficacité potentielle de base SD/SD séronégatif[a])

Intervalle de dosage	Évènement dans le groupe vacciné (AZD1222) n/N (%)	Évènements dans le groupe témoin (MenACWY) n/N (%)	Efficacité potentielle du vaccin (IC à 95 %)
22 jours ou plus après la première dose[b]			
	14/3 060 (0,5 %)	15/3 064 (0,5 %)	6,6 % (-93,5 à 54,9 %)
15 jours ou plus après la deuxième dose[c]			
Tout intervalle	8/2 377 (0,3 %)	11/2 340 (0,5 %)	26,9 % (-81,5 à 70,6 %)
4 à 12 semaines	S.O.	S.O.	37,7 % (-90,1 à 79,6 %)
Plus de 12 semaines	S.O.	S.O.	-4,3 % (-416,5 à 79 %)

[a] Participants sans preuve préalable d'une infection par le SRAS-CoV-2 à l'inclusion; tous les bénéficiaires du vaccin SD/SD (ou les témoins respectifs).
[b] Basé sur les données à la date limite du 4 novembre 2020
[c] Basé sur les données à la date limite du 7 décembre 2020

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Une analyse ponctuelle supplémentaire associant des participants à l'étude atteints d'une infection asymptomatique par le SRAS-CoV-2 ou présentant des symptômes inconnus n'a pas non plus permis de démontrer l'efficacité potentielle du schéma SD/SD (3,9 %, IC à 95 % : -72,1 à 46,4 %), sur la base de l'identification de 22 cas dans le groupe vacciné et de 23 cas dans le groupe témoin 15 jours ou plus après la deuxième dose.

Immunogénicité

Environ 15 % de l'ensemble des analyses de sécurité ont été ciblés pour être inclus dans l'ensemble d'analyses d'immunogénicité. Ces analyses ont combiné les données probantes des schémas posologiques SD/SD et LD/SD et peuvent ne pas correspondre complètement aux données des études individuelles.

Réponses immunitaires humorales
Les réponses des anticorps, qu'ils se lient ou se neutralisent, diffèrent selon que les receveurs du vaccin sont séronégatifs ou séropositifs. Comparativement aux receveurs séronégatifs, les receveurs du vaccin qui étaient séropositifs au départ ont présenté des titres d'anticorps élevés 28 jours après la première dose. Les receveurs séronégatifs ont présenté une augmentation des réponses immunitaires 28 jours après la deuxième dose. En revanche, les receveurs séropositifs ont eu des réponses immunitaires réduites après la deuxième dose, par rapport aux réponses après la première dose. Toutefois, les réponses immunitaires des receveurs séropositifs étaient toujours plus élevées que celles des receveurs séronégatifs. Le mécanisme à l'origine de ces différences et leur impact possible sur les efficacités potentielle et réelle des vaccins restent incertains. Un article récemment publié contient des données probantes supplémentaires sur les réponses humorales[128].

Les réponses des anticorps, qu'ils soient liants ou neutralisants, étaient plus faibles chez les adultes âgés (de plus de 65 ans) que chez les jeunes adultes après les première et deuxième doses de vaccin. Sans corrélat de protection, l'importance de ces différences dans les réponses des anticorps n'est pas claire.

Réponses immunitaires à médiation cellulaire
Des réponses immunitaires à médiation cellulaire ont été provoquées par ce vaccin. La première dose a provoqué un biais Th-1 des lymphocytes T CD4+ dans les groupes d'âge plus jeunes et plus âgés. Les jeunes vaccinés ont présenté des réponses immunitaires cellulaires plus élevées que les groupes plus âgés. La deuxième dose de vaccin n'a notamment pas augmenté les réponses immunitaires cellulaires. Le mécanisme et l'impact sur les efficacités potentielle et réelle des vaccins restent incertains.

Réponses immunitaires anti-vecteurs
On ne sait pas exactement dans quelle mesure la population canadienne est déjà immunisée contre un vecteur vaccinal à base d'adénovirus et quel impact cela pourrait avoir sur l'innocuité et l'efficacité potentielle des vaccins à base d'adénovirus. On ne sait pas non plus dans quelle mesure l'immunisation par des vaccins à base d'adénovirus provoque des réponses immunitaires antivectorielles et quel impact cela pourrait avoir sur les doses de rappel homologues ou hétérologues des vaccins à base d'adénovirus. Les données probantes d'un vaccin à vecteur viral basé sur l'adénovirus humain de type 5 (non autorisé au Canada) ont indiqué que les receveurs du vaccin ayant une forte immunité préexistante au vecteur adénovirus avaient des réponses immunitaires anti-SRAS-CoV-2 plus faibles [144]. Le vaccin contre la COVID-19 d'AstraZeneca est composé d'un vecteur à adénovirus de chimpanzé modifié (ChAd).

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AstraZeneca n'a trouvé aucune corrélation entre les réponses des anticorps neutralisants anti-ChAd et les réponses immunitaires anti-SRAS-CoV-2. AstraZeneca a aussi trouvé que les niveaux d'anticorps neutralisants n'ont pas été renforcés après la deuxième dose. Toutefois, la neutralisation n'est pas la seule réponse immunitaire anti-vecteur qui pourrait avoir un impact sur l'immunité induite par le vaccin. On ignore encore si les réponses immunitaires au vecteur ChAd auront un impact sur les efficacités potentielle et réelle de ce vaccin.

Innocuité du vaccin et effets secondaires suivant l'immunisation

Les données probantes sur l'innocuité sont fondées sur des analyses intermédiaires de 23 745 participants dont 12 021 ont reçu au moins une dose du vaccin contre la COVID-19 d'AstraZeneca et 11 724 ont reçu le témoin. Les analyses d'innocuité ont été menées dans différents ensembles d'analyse. Les ÉI sollicités survenant dans les 7 jours suivant une dose ont été évalués chez 2 648 personnes ayant reçu au moins une dose de vaccin (SD) et chez 2 497 personnes témoins. Environ un tiers des participants à l'étude ont reçu leur deuxième dose de vaccin dans les six semaines suivant la première. La majorité (environ 90 %) des participants à l'étude dans la cohorte de sécurité avaient moins de 65 ans. La durée médiane du suivi était de 105 jours après la première dose et de 62 jours après la deuxième dose.

Réactions locales sollicitées
Des ÉI au site d'injection local ont été signalés par 74,7 % des participants évalués dans les 7 jours suivant l'administration d'une dose de vaccin. La douleur et la sensibilité étaient les réactions les plus fréquemment signalées (54,2 % et 63,7 %, respectivement), suivies de la chaleur (17,7 %), des ecchymoses (17,3 %), de la rougeur (14 %), du prurit (12,7 %) et du gonflement (10 %). La plupart des réactions locales sollicitées chez les participants ayant reçu le vaccin étaient d'intensité légère ou modérée; des réactions de Stade 3 ou 4 ont été déclarées par 9,5 % ou moins des participants. Aucun ÉI de S4 n'a été déclaré. Les réactions locales étaient généralement plus légères et moins fréquentes après la deuxième dose du vaccin. Selon l'intervalle entre les doses, la réactogénicité du vaccin était plus faible chez les participants qui ont reçu la deuxième dose dans les 6 semaines suivant la première (38 % contre 58,3 % à 74,3 %, lorsque la deuxième dose a été administrée au bout de 6 semaines ou plus).

Réactions systémiques sollicitées
Des ÉI systémiques sollicités ont été signalés par 73 % des participants évalués dans les 7 premiers jours suivant l'administration d'une dose de vaccin. Les ÉI systémiques sollicités les plus courants étaient la fatigue (53,1 %) et les maux de tête (52,6 %). Les autres ÉI systémiques sollicités fréquemment signalés sont les suivants : douleurs musculaires (44 %), malaises (44,2 %), fébrilité (33,6 %), frissons (31,9 %), douleurs articulaires (26,4 %), nausées (21,9 %) et fièvre de 38 °C ou plus (7,9 %). Dans l'ensemble, la fréquence des réactions de Stade 3 ou 4, quelles qu'elles soient, ne dépassait pas 8,3 %. Le seul évènement de Stade 4 signalé était une fièvre de plus de 40 °C. Dans l'ensemble des groupes d'étude, les ÉI étaient plus légers et moins fréquents après la deuxième dose de vaccin. Selon l'intervalle entre les doses, la réactogénicité du vaccin était plus faible chez les participants qui ont reçu la deuxième dose moins de 6 semaines suivant la première (37,6 % contre 49,2 % à 67,1 %, lorsque la deuxième dose a été administrée au bout de 6 semaines ou plus).

Évènements indésirables graves non sollicités
Des ÉIG ont été signalés par moins de 1 % des participants à l'étude et étaient similaires au sein du groupe vacciné et du groupe témoin (0,7 % et 0,8 %, respectivement). Il n'y a pas eu de déséquilibres évidents par classe de système d'organe (CSO). Les ÉIG les plus fréquemment

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signalés selon la CSO étaient les infections et infestations (0,1 % contre 0,2 %), les blessures, les empoisonnements et les complications liées aux procédures (moins de 0,1 % contre 0,1 %).

Les chercheurs de l'étude ont considéré que deux ÉIG (pyrexie et myélite transverse) chez les personnes ayant reçu le vaccin étaient liés au vaccin. Le cas de pyrexie (40,5 °C) est survenu 2 jours après la première dose et s'est résolu le jour même après l'administration d'acétaminophène. L'évènement de myélite transverse est survenu chez une femme de 37 ans ayant des antécédents familiaux de Charcot-Marie-Tooth de type 1a (mère et frère). La participante a reçu deux doses du vaccin à l'étude à 77 jours d'intervalle. Des changements sensoriels et des maladresses sont apparus deux semaines après la deuxième dose. L'imagerie par résonance magnétique a montré une lésion correspondant à une myélite transverse ou à un infarctus du rachis antérieur. Un troisième ÉIG a été constaté à l'origine (augmentation de la protéine C-réactive). Toutefois, après la date limite, le chercheur a mis à jour la causalité de l'ÉIG lié à l'augmentation de la protéine C-réactive et a indiqué qu'elle n'était pas associée au traitement.

Autres évènements indésirables graves

Évènements de démyélinisation

Un cas de sclérose en plaques s'est produit chez une femme de 37 ans, qui a développé des symptômes sensoriels environ 10 jours après la première (et unique) vaccination. L'épisode clinique a duré trois semaines. Un suivi ultérieur par IRM de la colonne vertébrale et du cerveau a montré une lésion rachidienne aiguë et des lésions cérébrales plus anciennes, révélant une sclérose en plaques préexistante, mais non reconnue auparavant.

Décès

Au total, 6 décès ont été signalés chez les participants à l'étude : 2 dans le groupe vacciné et 4 dans le groupe témoin. Les deux décès de personnes ayant reçu le vaccin étaient attribuables à un néoplasme malin et à une pneumonie fongique, mais aucun n'a été considéré comme lié à l'intervention des chercheurs.

Thrombocytopénie thrombotique immunitaire induite par le vaccin

De rares cas de graves caillots sanguins, y compris la thrombose des sinus veineux cérébraux (CVST), associés à la thrombocytopénie ont été signalés au Canada et à l'échelle mondiale après l'utilisation autorisée du vaccin contre la COVID-19 d'AstraZeneca. Les cas se sont généralement produits entre les jours 4 et 28 suivant l'administration du vaccin. Cet ÉI est appelé TTIV (thrombocytopénie thrombotique immunitaire induite par le vaccin). Le mécanisme d'action est semblable à celui de la thrombocytopénie induite par l'héparine (TIH). Le mécanisme exact par lequel les vaccins à vecteur viral contre la COVID-19 peuvent déclencher la TTIV est toujours à l'étude. À l'heure actuelle, aucun facteur de risque n'a été systématiquement signalé chez les personnes ayant développé la TTIV. La fréquence de cet ÉI doit encore être confirmée, mais on l'avait le plus couramment estimé entre 1/26 000 et 1/100 000 personnes ayant reçu une première dose du vaccin contre la COVID-19 d'AstraZeneca, bien que ce taux continue d'évoluer et puisse augmenter. Selon les données probantes disponibles du 1 juin 2021, l'ASPC a estimé le taux de TTIV au Canada à 1 sur 73 000 doses administrées. Toutefois, à mesure que les recherches se poursuivent, ce taux pourrait s'élever à 1 par 50 000 personnes ayant reçu le vaccin contre la COVID-19 de COVISHIELD. La fréquence du STT après une deuxième dose du vaccin d'AstraZeneca est actuellement signalée comme étant d'environ 1 pour 600 000 à 1 pour 750 000 personnes vaccinées avec une deuxième dose, sur la base des données de surveillance de l'innocuité des vaccins au R.-U., mais cela continue d'évoluer [2]. Une collecte de renseignements supplémentaires est en cours pour mieux caractériser le taux de TTIV. Selon l'information

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disponible, le taux de létalité de la TTIV se situe entre 20 et 50 %. Toutefois, il peut varier avec une sensibilisation accrue à l'ÉI et un traitement précoce approprié.

Efficacité réelle chez les adultes de 65 ans et plus

En l'absence de données suffisantes issues d'essais cliniques sur l'efficacité du vaccin d'AstraZeneca chez les personnes âgées de 65 ans et plus, une revue de trois études d'observation au R.-U. publiées sous forme de préimpression sur l'efficacité réelle du vaccin dans ce groupe d'âge a été réalisée afin d'éclairer les recommandations du CCNI dans ce groupe d'âge. Les conclusions de cette revue sont résumées ci-dessous.

Les trois études d'observation ont évalué une dose du vaccin de Pfizer-BioNTech ou des vaccins d'AstraZeneca au R.-U. Les résultats ci-dessous ne concernent que la partie sur le vaccin d'AstraZeneca des études. Les études ont été menées pendant la période où le variant B.1.1.7 (alpha) devenait rapidement la souche dominante en circulation dans leurs régions géographiques respectives. Environ 50 % des échantillons de laboratoire se sont révélés avoir un profil conforme au variant B.1.1.7 (alpha) début décembre 2020 en Angleterre, et 43 % en Écosse début janvier 2021. De la mi-février à la fin février, le variant B.1.1.7 (alpha) représentait presque 100 % des souches en circulation en Angleterre, et était considéré comme la souche dominante en Écosse.

Sommaire général des données probantes
Chez les adultes de 65 ans et plus, des données d'observation provenant du R.-U. ont montré une réduction du risque de maladie symptomatique et d'hospitalisation à partir de deux semaines après une dose du vaccin d'AstraZeneca.

Sommaire détaillé de chaque étude

1. Hyams et al., Assessing the Effectiveness of BNT162b2 and ChAdOx1nCoV-19 COVID-19 Vaccination in Prevention of Hospitalisations in Elderly and Frail Adults: A Single Centre Test Negative Case-Control Study. **Préimpression** de SSRN-Lancet. 3 mars 2021. https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

Description : Étude cas-témoins à test négatif de personnes hospitalisées de 80 ans et plus (dont beaucoup étaient fragiles avec des comorbidités) dans deux hôpitaux de Bristol, au R.-U. La vaccination a été déterminée par couplage d'enregistrements et un ajustement a été effectué pour un certain nombre de facteurs. L'efficacité du vaccin contre l'hospitalisation a été évaluée chez ceux qui avaient été vaccinés au moins 14 jours avant l'apparition des symptômes.

Résultats : L'efficacité d'une dose du vaccin 80,4 % (IC 95 % : 36,4 - 94,5 %) contre l'hospitalisation survenant dans les 14 jours ou plus (maximum de 53 jours) après une dose de vaccin contre la COVID-19 d'AstraZeneca chez les patients de 80 ans et plus.

Examen :

- La vaccination a été déterminée par le couplage des dossiers et les informations cliniques ont été obtenues à partir des dossiers par des personnes qui sont aveugles aux résultats du SRAS-CoV-2 des participants, ce qui constitue des points forts de l'analyse. Ce sont les points forts méthodologiques de cette étude.

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- Les auteurs ont effectué une analyse de sensibilité portant sur les personnes dont les symptômes sont apparus moins de 14 jours après la vaccination et n'ont pas constaté d'effet, ce qui était prévisible car il s'agit d'une période trop précoce pour que le vaccin soit efficace, et qui renforce les différences observées 14 jours ou plus après la vaccination.
- Les cas et les témoins admissibles ont été sélectionnés à partir de la liste des admissions médicales, et la manière dont cela a été fait n'est pas claire.
- Des analyses distinctes semblent avoir été menées pour AstraZeneca et Pfizer-BioNTech, mais la manière dont les sujets de chaque analyse ont été assignés n'est pas claire.

2. Lopez Bernal et al., Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. medRxiv. **Préimpression**. 2 mars 2021. https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

Description : Étude cas-témoins à test négatif utilisant des données de surveillance reliées au R.-U. parmi les patients de 70 ans et plus. Les tests PCR ont été effectués dans les 10 jours suivant l'apparition des symptômes. Pour ceux qui ont été vaccinés, les cas et les témoins ont été évalués en fonction du temps écoulé entre la vaccination et l'apparition des symptômes, en tenant compte d'un certain nombre de facteurs. L'impact de la vaccination sur l'hospitalisation des personnes âgées de 80 ans et plus a également été évalué chez les personnes dont le test était positif.

Résultats : L'efficacité d'une dose du vaccin contre l'infection symptomatique par le SRAS-CoV-2 confirmée par PCR dans l'analyse ajustée était de 22 % (IC 95 % : 11 – 32 %) 14 à 20 jours après la vaccination et a progressivement augmenté jusqu'à 73 % (IC 95 % : 27 – 90 %) 35 jours ou plus (maximum 48 jours) après la vaccination. En plus de l'effet contre la maladie symptomatique, chez les personnes âgées de 80 ans et plus, il y avait une protection supplémentaire de 37 % contre l'hospitalisation dans les 14 jours suivant un test positif chez ceux qui étaient à 14 jours ou plus de leur première dose de vaccin par rapport à ceux qui n'étaient pas vaccinés.

Examen :

- Le couplage des enregistrements à l'aide de grands ensembles de données est un point fort de cette étude.
- Un nombre relativement faible de sujets a été inclus dans l'analyse du vaccin contre la COVID-19 d'AstraZeneca à des périodes ultérieures, en particulier dans la période de 35 jours ou plus après la vaccination, lorsque l'efficacité du vaccin était la plus élevée.
- Les rapports de cotes non ajustés et ajustés sont considérablement différents dans l'analyse du vaccin contre la COVID-19 d'AstraZeneca, reflétant les différences entre les groupes d'étude.
- Les informations démographiques et cliniques concernant les cas et les témoins et les personnes vaccinées et non vaccinées n'ont pas été fournies.

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3. Vasileiou et al. Effectiveness of first dose COVID-19 vaccines against hospital admissions in Scotland effectiveness findings from Scotland: national prospective cohort study of 5.4 million people. **Préimpression** de SSRN-Lancet. 19 février 2021. https://papers.ssm.com/sol3/papers.cfm?abstract_id=3796835

Description : Une étude de cohorte observationnelle prospective utilisant le couplage d'enregistrements entre les bases de données, y compris les dossiers de vaccination, d'hospitalisation et de laboratoire pour la population en Écosse, avec ajustement pour un certain nombre de facteurs. Bien que l'étude ait inclus les personnes âgées de 18 ans et plus, le vaccin d'AstraZeneca a été principalement administré aux participants âgés de 65 ans et plus. L'efficacité du vaccin en fonction de l'âge est fournie mais ne faisait pas de distinction entre les vaccins de Pfizer et d'AstraZeneca, qui ont tous deux été étudiés, bien que les personnes âgées de 80 ans et plus aient principalement reçu le vaccin d'AstraZeneca.

Résultats : L'efficacité d'une dose du vaccin d'AstraZeneca contre l'hospitalisation était de 74 % (IC 95 % : 66 – 81 %) 14 à 20 jours après la vaccination et augmentait jusqu'à 94 % (IC 95 % : 73 – 99 %) 28 à 34 jours après la vaccination. Chez les patients de 80 ans et plus, les auteurs ont constaté un pic de l'efficacité vaccinale (VE) de 81 % (IC 95 % : 65 – 90 %) contre l'hospitalisation dans les 28 à 34 jours après une dose de vaccin qui était principalement le vaccin d'AstraZeneca.

Examen :
En raison de préoccupations liées aux faiblesses méthodologiques de cette étude, le CCNI n'a pas utilisé ces résultats pour étayer ses recommandations.

- L'efficacité du vaccin d'AstraZeneca COVID-19 contre l'hospitalisation était élevée (70 %) 7 à 13 jours après la vaccination, ce qui est biologiquement invraisemblable, car 7 à 13 jours seraient trop tôt pour s'attendre à une protection contre l'infection ou l'hospitalisation à la suite de la vaccination, ce qui suggère des problèmes méthodologiques et rend difficile l'interprétation des résultats élevés d'efficacité du vaccin à des périodes ultérieures (94 % entre 28 et 34 jours).
- Le nombre de personnes vaccinées avec le vaccin contre la COVID-19 d'AstraZeneca est faible dans la période de 28 jours et plus après la vaccination.
- Comme le déploiement du vaccin a été initialement conçu en fonction des groupes prioritaires présentant un risque plus élevé de maladie sévère ou d'exposition, les ajustements des facteurs de confusion potentiels effectués au cours des analyses statistiques n'ont peut-être pas permis de contrôler de manière adéquate toutes les différences entre les personnes vaccinées et non vaccinées. Aucune comparaison des facteurs démographiques et de risque entre les groupes vaccinés et non vaccinés n'a été fournie séparément pour chaque vaccin.
- L'admission à l'hôpital a été définie comme suit : COVID-19 comme principale cause d'admission ou hospitalisation dans les 28 jours suivant un test PCR SARS-CoV-2 positif. L'admission à l'hôpital pour le COVID-19 est un critère moins spécifique pour déterminer l'hospitalisation pour le COVID-19 et la proportion de cas définis selon ce critère n'est pas fournie.
- Bien que l'efficacité vaccinale spécifique au produit et l'efficacité vaccinale spécifique à l'âge soient toutes deux fournies séparément, l'efficacité vaccinale spécifique au produit par âge n'est pas fournie.
- Le couplage des enregistrements à l'aide d'un vaste ensemble de données est un point fort de cette étude.

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ANNEXE D : RÉSUMÉ DES DONNÉES PROBANTES DES ESSAIS CLINIQUES POUR LE VACCIN CONTRE LA COVID-19 DE JANSSEN

Les données des essais de Phases 1, 2 et 3 étaient disponibles au moment de l'autorisation du vaccin de Janssen. Des données probantes sur l'efficacité potentielle, l'immunogénicité et l'innocuité sont disponibles pour les adultes de 18 ans et plus. L'essai de Phase 3 a porté sur 44 325 participants qui ont été randomisés (1:1) et qui ont reçu soit le vaccin (1 dose de 5×10^{10} particules virales), soit un placebo. Les données présentées ci-dessous correspondent à une médiane de deux mois après l'achèvement de la série (une dose). Les données probantes tirées de la surveillance et des études post-commercialisation se trouvent dans le corps de la présente déclaration.

Efficacité potentielle

COVID-19 symptomatique

Les estimations de l'efficacité potentielle contre la COVID-19 modérée à sévère/critique étaient le principal résultat de l'essai de Phase 3. Étant donné la définition relativement large de la COVID-19 modérée adoptée pour l'essai clinique, moins de 1 % des cas repérés cadraient avec la définition des cas bénins. Par conséquent, près de tous les cas de la COVID-19 symptomatique observés ont été englobés dans la définition modérée à sévère/critique de la maladie.

Les critères coprimaires de l'analyse de l'efficacité potentielle du vaccin sont la prévention de la première apparition d'une infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 et au moins 28 jours après la vaccination. L'analyse primaire est étayée par des analyses par sous-groupe des critères primaires stratifiés selon le pays à l'étude, le groupe d'âge, la présence de comorbidités associées à un risque accru d'évolution vers un cas de COVID-19 sévère, le sexe et la race ou l'ethnicité. L'efficacité potentielle contre une infection à la COVID-19 symptomatique sévère/critique confirmée se manifestant au moins 14 et au moins 28 jours après la vaccination sont des critères secondaires, également soutenus par des analyses stratifiées selon les mêmes sous-groupes que le critère primaire. Des analyses supplémentaires de l'efficacité potentielle dans les cas de COVID-19 sévère/critique comprennent des examens des cas s'étant soldés par une intervention médicale, des hospitalisations et des décès. Pour les critères tant primaires que secondaires, des courbes de l'incidence cumulative sont utilisées pour examiner le début et la durée potentiels de l'efficacité du vaccin. Des analyses exploratoires de l'efficacité potentielle du vaccin contre l'infection par le SRAS-CoV-2 asymptomatique ou non détectée, de la gravité des symptômes et de la charge virale sont également étudiées. Certains résultats de ces analyses sont présentés dans cette annexe.

Un certain nombre d'analyses sont effectuées dans l'ensemble d'analyse complet, qui correspond aux participants à l'étude qui ont été randomisés et ont reçu l'intervention de l'étude (vaccin ou placebo), indépendamment de la survenue d'infractions au protocole ou du statut sérologique au départ. Cependant, la plupart des analyses primaires de l'efficacité potentielle ont été menées dans l'ensemble conforme au protocole, ce qui correspond aux participants à l'étude qui ont été randomisés, ont reçu l'intervention de l'étude (vaccin ou placebo), étaient séronégatifs au moment de la vaccination et ne présentaient pas d'infractions majeures au protocole

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considérées comme étant susceptibles d'influer sur l'efficacité potentielle du vaccin. De nombreuses analyses par sous-groupe sont réalisées dans l'ensemble conforme au protocole au moyen de cas de COVID-19 confirmés de manière centralisée, mais elles sont répétées à l'aide d'un ensemble de données plus large comprenant à la fois les cas confirmés de manière centralisée et les cas ayant obtenu un résultat positif au test PCR effectué à un site de dépistage local qui n'avait pas encore été confirmé par l'installation de test central de l'essai clinique à la date limite de réception des données pour l'analyse. L'utilisation des cas confirmés localement est étayée par la démonstration d'une concordance élevée (90,3 %) des résultats de la PCR entre les installations de test locales et centrales de l'essai clinique. **Sauf indication contraire, toutes les analyses de l'efficacité potentielle présentées dans ce résumé relèvent de l'ensemble conforme au protocole des participants à l'étude, sur la base d'une date limite de réception des données fixée au 22 janvier 2021.**

Infection à la COVID-19 symptomatique confirmée modérée à sévère/critique

La définition de COVID-19 modérée utilisée dans l'essai clinique était très large. Comme tel, les cas respectant la définition de COVID-19 modérée à sévère/critique ont représenté plus de 99 % de tous les cas de COVID-19 symptomatique identifiée dans l'essai. Les estimations de l'efficacité potentielle du vaccin contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination se chiffrent à 66,9 % et à 66,1 %, respectivement (Tableau 15).

Tableau 15. Efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, ensemble conforme au protocole

Résultats coprimaires	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥14 jours après la vaccination					
Infection à la COVID-19 modérée à sévère/critique	116/19 514	3 116,6	348/19 544	3 096,1	66,9 % (59,0 à 73,4)
≥28 jours après la vaccination					
Infection à la COVID-19 modérée à sévère/critique	66/19 306	3 102,0	193/19 178	3 070,7	66,1 % (55,0 à 74,8)

Source : Présentation du fabricant Janssen à Santé Canada, module 2.5 : Aperçu clinique, Tableaux 5 et 6

Infection à la COVID-19 symptomatique confirmée sévère/critique

Les estimations de l'efficacité du vaccin contre l'infection à la COVID-19 symptomatique confirmée sévère/critique sont de 76,7 % se manifestant au moins 14 jours après la vaccination et de 85,4 % se manifestant au moins 28 jours après la vaccination (Tableau 16).

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Tableau 16. Efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, ensemble conforme au protocole

Résultats coprimaires	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥14 jours après la vaccination					
Infection à la COVID-19 sévère/critique	14/19 514	3 125,1	60/19 544	3 122,0	76,7 % (54,6 à 89,1)
≥28 jours après la vaccination					
Infection à la COVID-19 sévère/critique	5/19 306	3 106,2	34/19 178	3 082,6	85,4 % (54,2 à 96,9)

Source : Présentation du fabricant Janssen à Santé Canada, module 2.5 : Aperçu clinique, Tableaux 5 et 6

Analyses des sous-groupes

Par pays d'étude

La période couverte par l'essai clinique était associée à l'émergence de nouveaux VP du SRAS-CoV-2 dans certains pays à l'étude. Au moment de la date limite de réception pour l'analyse primaire, des données préliminaires de séquençage génétique étaient disponibles pour une proportion d'isolats des cas du Brésil, de l'Afrique du Sud et des É.-U. (Tableau 17). Aucun variant du SARS-CoV-2 provenant des souches B.1.1.7 (alpha) ou P.1 (gamma) n'a été détecté dans les isolats séquencés.

Tableau 17. Résultats du séquençage génétique pour le variant préoccupant, de septembre à décembre 2020

Pays	Cas déclarés N	Cas séquencés n (%)	Résultats du séquençage
Brésil	179	124 (69,2)	86/124 (69,4 %) – variant 20J/501Y,V3 de la souche P.2 (zêta) 38/124 (30,6 %) – séquence de référence Wuhan-Hu1+D614G
Afrique du Sud	136	91 (66,9)	86/91 (94,5 %) – variant 20H/501Y,V2 de la souche B.1.351 (béta)
États-Unis	268	197 (73,5)	190/197 (96,4 %) – séquence de référence Wuhan-Hu1+D614G

Source : Présentation du fabricant Janssen à Santé Canada, module 2,5 : Aperçu clinique, Section 4,1,3,1, Cadre épidémiologique de l'étude

Les analyses de l'efficacité potentielle du vaccin par pays ont été menées dans ceux comptant plus de 100 cas déclarés (É.-U., 247; Brésil, 153; Afrique du Sud, 133) à l'aide d'un ensemble de données comprenant à la fois des cas de COVID-19 confirmés centralement par PCR et des cas ayant obtenu un résultat positif au test PCR effectué à un site local, mais non encore confirmés par l'instance centrale de l'essai à la date limite de réception des données d'analyse. L'inclusion des cas confirmés localement a été justifiée par la démonstration d'une concordance élevée (90,3 %) des résultats de la PCR entre l'instance centrale et les sites locaux. Les estimations de l'efficacité ponctuelle du vaccin par pays contre l'infection à la COVID-19 symptomatique à la fois confirmée de modérée à sévère/critique et de sévère/critique avec une apparition au moins 14 jours et au moins 28 jours après la vaccination sont équivalentes ou supérieures aux estimations globales de l'efficacité à ces points dans le temps (Tableau 18). L'unique exception est

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l'estimation ponctuelle de l'efficacité potentielle du vaccin pour l'Afrique du Sud avec une apparition au moins 14 jours après la vaccination.

Tableau 18. Efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique et sévère/critique selon le pays pour les pays comptant plus de 100 cas modérés à sévères/critiques et des cas confirmés par PCR à l'instance centrale et aux sites locaux

Pays	Apparition post-vaccination	Définition de la COVID-19	
		modéré à sévère /critique Efficacité (IC à 95 %)	sévère /critique Efficacité (IC à 95 %)
É.-U.	≥14 jours	74,4 % (65,0 à 81,6)	78,0 % (33,1 à 94,6)
	≥28 jours	72,0 % (58,2 à 81,7)	85,9 % (-9,4 à 99,7)
Brésil	≥14 jours	66,2 % (51,0 à 77,1)	81,9 % (17,0 à 98,1)
	≥28 jours	68,1 % (48,8 à 80,7)	87,6 % (7,8 à 99,7)
Afrique du Sud	≥14 jours	52,0 % (30,3 à 67,4)	73,1 % (40,0 à 89,4)
	≥28 jours	64,0 % (41,2 à 78,7)	81,7 % (46,2 à 95,4)

Source : Présentation du fabricant Janssen à Santé Canada, module 2.5 : Aperçu clinique, Tableau 11.

Par groupe d'âge

L'efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination a été évaluée dans divers groupes d'âge (Tableau 19).

Tableau 19. Efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, par groupe d'âge, ensemble conforme au protocole

Groupe d'âge (années)	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥14 jours après la vaccination					
De 18 à 39 ans	47/4 356	775,3	122/4 330	762,1	62,1 % (46,6 à 73,6)
De 40 à 59 ans	48/8 394	1 331,5	138/8 452	1 332,9	65,2 % (51,3 à 75,5)
60 à 69 ans	19/4 800	722,9	65/4 907	732,2	70,4 % (50,0 à 83,2)
70 à 79 ans	2/1 768	259,5	23/1 650	239,2	92,0 % (67,6 à 99,1)
≥ 80	0/196	27,42	0/205	29,8	S.O*
<60 ans (c.-à-d.,18 à 59 ans)	95/12 750	2 106,8	260/12 782	2 095,0	63,7 % (53,9 à 71,6)
<65 (c.-à-d., 18 à 64 ans)	107/15 544	2 530,3	297/15 552	2 511,2	64,2 % (55,3 à 71,6)
≥60 ans	21/6 764	1 009,8	88/6 762	1 001,2	76,3 % (61,6 à 86,0)
≥ 65 ans	9/3 970	586,3	51/3 992	584,9	82,4 % (63,9 à 92,4)
≥75 ans	0/751	88,4	8/690	99,2	100,0 % (45,9 à 100,0)
≥28 jours après la vaccination					
De 18 à 39 ans	29/4 316	772,4	84/4 254	756,6	66,2 % (47,9 à 78,6)
De 40 à 59 ans	23/8 301	1 325,2	68/8 273	1 320,4	66,3 % (45,2 à 80,0)
60 à 69 ans	12/4 749	719,3	32/4 833	727,1	62,1 % (24,4 à 82,2)
70 à 79 ans	2/1 746)	257,8	9/1 620	237,2	79,6 % (1,2 à 97,9)
≥ 80 ans	0/194	27,3	0/198	29,3	S.O.
<60 ans (c.-à-d., 18 à 59 ans)	52/12 617	2 097,6	152/12 527	2 077,0	66,1 % (53,3 à 75,8)
<65 (c.-à-d., 18 à 64 ans)	60/15 378	2 518,7	170/15 253	2 490,1	65,1 % (52,9 à 74,5)

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≥60 ans	14/6 689	1 004,4	41/6 651	993,6	66,2 % (36,7 à 83,0)
≥ 65 ans	6/3 928	583,3	23/3 925	580,5	74,0 % (34,4 à 91,4)
≥75 ans	0/740	106,4	3/673	98,1	S.O.

*S.O. = Sans objet; on n'a pas établi d'estimations de l'efficacité potentielle du vaccin puisque moins de six événements ont été signalés.
Source : Présentation du fabricant Janssen à Santé Canada, module 2,5 : Aperçu clinique, Figures 30 et 31.

L'efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination a été calculée pour quatre groupes d'âge : 18 à 59 ans, 18 à 64 ans, 60 et plus et 65 ans et plus (Tableau 20).

L'analyse a été répétée à l'aide d'un ensemble plus large de données comprenant à la fois les cas confirmés de COVID-19 et les cas ayant obtenu un résultat positif au test PCR effectué à un site de dépistage local à l'intérieur du pays. Les estimations de l'efficacité potentielle du vaccin chez les participants âgés de 65 ans et plus à au moins 14 jours et à au moins 28 jours après la vaccination sont passées à 71,4 % et à 70,1 %, respectivement.

Tableau 20. Efficacité potentielle contre l'infection à la COVID-19 symptomatique confirmée sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, par groupe d'âge, ensemble conforme au protocole

Groupe d'âge (années)	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥14 jours après la vaccination					
18 à 59 ans	8/12 750	2 114,3	41/12 782	2 115,1	80,5 % (57,8 à 92,1)
18 à 64 ans	11/15 544	2 538,5	50/15 552	2 533,8	78,0 % (57,3 à 89,7)
≥60 ans	6/6 764	1 01,7	19/6 762	1 006,9	68,5 % (18,1 à 89,7)
≥ 65 ans	3/3 970	586,6	10/3 992	588,3	69,9 % (-16,8 à 94,7)
≥28 jours après la vaccination					
18 à 59 ans	2/12 617	2 101,0	24/12 527	2 086,7	91,7 % (66,7 à 99,1)
18 à 64 ans	2/15 378	2 522,8	28/15 253	2 500,9	92,9 % (71,9 à 99,2)
≥60 ans	3/6 689	1 005,1	10/6 651	995,9	70,3 % (-15,5 à 94,7)
≥ 65 ans	3/3 928	583,4	6/3 925	581,7	50,1 % (-133,4 à 91,9)

Source : Présentation du fabricant Janssen à Santé Canada, module 2,5 : Aperçu clinique, Figures 32 et 33

Par comorbidité

Dans l'essai clinique, la présence de comorbidités a été définie comme étant un participant à l'étude présentant au départ une ou plusieurs affections médicales associées à un risque accru d'évolution vers un cas de COVID-19 sévère (par exemple, asthme, maladie cérébrovasculaire, hypertension, maladie respiratoire, maladie du foie et obésité). Chez les participants avec et sans comorbidités, l'efficacité potentielle a été évaluée contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique et contre l'infection à la COVID-19 symptomatique confirmée sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination (Tableau 21).

En répétant l'analyse avec l'ensemble de données plus large des cas de COVID-19 confirmés de manière centralisée et localement à l'intérieur du pays, on a estimé que l'efficacité potentielle du vaccin contre (a) l'infection à la COVID-19 confirmée modérée à sévère/critique et (b) contre l'infection à la COVID-19 sévère/critique chez les participants présentant des comorbidités était de 58,6 % (IC à 95 % : 40,6 à 71,6 %) et de 75,2 % (IC à 95 % : 32,0 à 92,7 %) pour une apparition au moins 28 jours après la vaccination.

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Tableau 21. Efficacité contre l'infection à la COVID-19 symptomatique confirmée (a) modérée à sévère/critique et (b) sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, selon la présence ou l'absence de comorbidités, ensemble conforme au protocole

Présence de comorbidités (oui/non)	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
(a) Infection à la COVID-19 modérée à sévère/critique					
≥14 jours après la vaccination					
Oui	47/7 777	1 140,0	126/7 798	1 133,7	62,9 % (47,8 à 74,1)
Non	69/11 737	1 976,6	222/11 746	1 962,5	69,1 % (59,4 à 76,8)
≥28 jours après la vaccination					
Oui	27/7 684	1 133,6	52/7 626	1 121,7	48,6 % (16,7 à 69,0)
Non	39/11 622	1 968,4	141/11 552	1 949,0	72,6 % (60,7 à 81,3)
b) Infection à la COVID-19 sévère/critique					
≥14 jours après la vaccination					
Oui	8/7 777	1 142,9	29/7 798	1 141,7	72,4 % (38,2 à 89,1)
Non	6/11 737	1 982,1	31/11 746	1 980,3	80,7 % (53,0 à 93,4)
≥28 jours après la vaccination					
Oui	4/7 684	1 135,0	12/7 626	1 124,2	67,0 % (-8,9 à 92,2)
Non	1/11 622	1 971,1	22/11 552	1 958,3	95,5 % (72,1 à 99,9)

Source : Présentation du fabricant Janssen à Santé Canada, module 2,5 : Aperçu clinique, Figures 30, 31, 32 et 33

Par statut sérologique

Cette analyse a été réalisée avec l'ensemble de données élargi comprenant les cas de COVID-19 confirmés de manière centralisée et localement et a permis d'estimer l'efficacité potentielle du vaccin contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique chez les participants à l'étude en fonction de leur statut sérologique au départ (Tableau 22).

Tableau 22. Efficacité contre l'infection à la COVID-19 symptomatique confirmée modérée à sévère/critique se manifestant au moins 14 jours et au moins 28 jours après la vaccination, y compris les cas confirmés à la fois de manière centralisée et non centralisée, par statut sérologique, ensemble conforme au protocole

Statut sérologique pour le SRAS-CoV-2 au départ	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥14 jours après la vaccination					
Indépendamment du statut initial	176/21 636	3 450,2	513/21 574	3 409,8	66,1 % (59,7 à 71,6 %)
Positif	3/2 122	336,3	4/2 030	320,8	28,5 % (-322,8 à 89,5)
Négatif	173/19 514	3 113,9	509/19 544	3 089,1	66,3 % (59,9 à 71,8)
≥28 jours après la vaccination					
Indépendamment du statut initial	114/21 424	3 436,3	326/21 199	3 385,9	65,5 % (57,2 à 72,4)
Positif	1/2 118	336,1	2/2 021	320,0	S.O.*
Négatif	113/19 306	3 100,3	324/19 178	3 065,9	65,5 % (57,2 à 72,4)

*S.O. = Sans objet; on n'a pas établi d'estimations de l'efficacité potentielle du vaccin puisque moins de six événements ont été signalés.

Source : Tableau 14, document d'information de la FDA pour la réunion du comité consultatif sur les vaccins et les produits biologiques connexes (26 février 2021).

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Hospitalisations

Une analyse a posteriori a évalué l'efficacité potentielle du vaccin contre les hospitalisations associées à la COVID-19. L'analyse portait sur des cas survenus au moins 1 jour, au moins 14 jours et au moins 28 jours après la vaccination chez des participants à l'étude séronégatifs au départ (Tableau 23). À chaque point temporel, l'analyse a été réalisée à partir (a) des cas de COVID-19 confirmés de manière centralisée uniquement et (b) des cas confirmés à la fois de manière centralisée et locale (« tout résultat positif au test PCR »).

Tableau 23. Efficacité contre les hospitalisations associées à la COVID-19 pour des symptômes apparus au moins 1, au moins 14 et au moins 28 jours après la vaccination

Population d'analyse	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
≥1 jour après la vaccination (FAS-SN)					
Cas confirmés	6	3 202,8	18	3 213,1	66,6 % (12,1 à 89,1)
Tout résultat positif au test PCR	6	3 202,8	42	3 211,6	85,7 % (66,1 à 95,0)
≥14 jours après la vaccination (conforme au protocole)					
Cas confirmés	2	3 125,8	11	3 125,9	81,8 % (16,7 à 98,0)
Tout résultat positif au test PCR	2	3 125,8	29	3 125,1	93,1 % (72,7 à 99,2)
≥28 jours après la vaccination (conforme au protocole)					
Cas confirmés	0	3 106,3	6	3 084,4	100,0 % (15,7 à 100,0)
Tout résultat positif au test PCR	0	3 106,3	16	3 083,9	100,0 % (74,3 à 100,0)

FAS-SN = Ensemble d'analyse complet, participants à l'étude entièrement randomisée avec administration documentée du vaccin à l'étude, séronégatifs au départ; PP = ensemble conforme au protocole
Source : Présentation du fabricant Janssen à Santé Canada, module 2.5 : Aperçu clinique, Tableau 10.

Décès

Dix-neuf décès ont été signalés au cours de l'essai clinique : 3 dans le groupe vacciné et 16 dans le groupe placebo. Sur les 19 décès, il a été établi qu'aucun dans le groupe vacciné n'était associé à la COVID-19, d'après les classifications de cas de COVID-19 de l'OMS, en combinaison avec un résultat positif à la RT-PCR, comparativement à 5 décès associés à la COVID-19 dans le groupe placebo. Les cinq décès survenus dans le groupe placebo concernaient des participants sud-africains présentant une ou plusieurs comorbidités associées à un risque accru d'évolution vers un cas sévère de COVID-19.

Infection par le SARS-CoV-2 asymptomatique ou non détectée

L'analyse de l'efficacité du vaccin contre l'infection par la COVID-19 asymptomatique ou non détectée (participants ne répondant pas à l'une des définitions de cas pour la COVID-19 symptomatique et ayant un résultat positif au test PCR ou sérologique) et contre la séroconversion a été réalisée à deux points dans le temps : avec une apparition 1 à 29 jours et 28 jours ou plus après la vaccination. Une analyse de sensibilité a également été réalisée pour chacun de ces résultats en éliminant les participants présentant des symptômes à tout moment depuis le dépistage et avant le résultat positif au test PCR ou sérologique (« sans symptômes antérieurs »).

L'estimation ponctuelle de l'efficacité potentielle du vaccin contre l'infection à la COVID-19 asymptomatique ou non détectée pour une apparition au moins 28 jours après la vaccination se

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chiffre à 59,7 % (et à 74,0 % après retrait des participants affichant des symptômes antérieurs) et contre une séroconversion s'élevant à 66,5 % (74,2 % après retrait des participants affichant des symptômes antérieurs) (Tableau 24). Les résultats de la séroconversion devraient être interprétés avec prudence, car il s'agit d'une analyse préliminaire fondée sur une durée de suivi limitée d'environ 29 % des participants à l'étude prévus pour l'analyse finale basée sur la sérologie au 71e jour.

Tableau 24. Efficacité contre l'infection par la COVID-19 asymptomatique et non détectée, et contre la séroconversion, avec une apparition 28 jours ou plus après la vaccination

Résultats	Groupe vacciné		Groupe placebo		Efficacité du vaccin (IC à 95 %)
	Cas (n/N)	Années-personnes	Cas (n/N)	Années-personnes	
Ensemble d'analyse complet, séronégatif au départ					
Infection par le SRAS-CoV-2 asymptomatique ou non détectée	22/19 301	3 099,70	54/19 162	3 064,2	59,7 % (32,8 à 76,6)
Infection par le SARS-CoV-2 asymptomatique ou non détectée *sans symptômes antérieurs*	10/19 301	3 098,0	38/19 162	3 061,5	74,0 % (46,8 à 88,4)
Ensemble sur le risque sérologique*					
Séroconversion	18/1 346	312,2	50/1 304	298,2	65,5 % (39,9 à 81,1)
Séroconversion *sans symptômes antérieurs*	10/1 346	310,9	37/1 304	296,6	74,2 % (47,1 à 88,6)

*Ensemble sur le risque sérologique = participants dont le résultat sérologique était disponible au 71e jour après la vaccination.
Source : Présentation du fabricant Janssen à Santé Canada, module 2.5 : Aperçu clinique, Tableau 12.

Immunogénicité

La majorité de l'analyse d'immunogénicité est basée sur les données d'un essai de Phase 1 qui a inclus deux cohortes d'adultes en bonne santé âgés de 18 à 55 ans et de 65 ans et plus. Dans chaque cohorte, il y avait deux niveaux de dose administrés en une ou deux doses. L'analyse ci-dessous provient d'une dose de la plus faible dose, soit de $5x10^{10}$ particules virales.

Réponses immunitaires humorales

Les réponses des anticorps ont été provoquées par une dose du vaccin de Janssen. Les anticorps de liaison et de neutralisation ont atteint un maximum au 29e jour et se sont maintenus jusqu'au 85e jour (dernier point d'évaluation dans le temps) dans la cohorte plus jeune. Dans la cohorte plus âgée, les réponses des anticorps de liaison étaient légèrement inférieures à celles de la cohorte plus jeune et ont été déclenchées plus lentement, augmentant du 15e au 57e jour (dernier point d'évaluation dans le temps). Les réponses des anticorps neutralisants étaient d'un niveau similaire à celles de la cohorte plus jeune. Elles ont été déclenchées dès le 15e jour et ont maintenu un plateau approximatif jusqu'au 57e jour. Les réponses des anticorps fonctionnels, déterminées par la fonction effectrice Fc, ont été déclenchées au maximum au 29e jour (le dernier jour de l'évaluation), à des niveaux similaires dans les deux cohortes d'âge.

On dispose de peu de données sur les personnes séropositives qui pourraient indiquer qu'elles ont une réponse forte à une seule dose de vaccin.

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On dispose également de données minimes démontrant une diminution de la réponse des anticorps neutralisants au variant viral B.1.1.7 (alpha).

Sans corrélat de protection, l'importance de ces différences dans les réponses des anticorps n'est pas claire.

Réponses immunitaires à médiation cellulaire
Les réponses immunitaires cellulaires ont été déclenchées par une dose de ce vaccin et étaient similaires dans les deux cohortes d'âge. Des réponses des lymphocytes T CD4+ spécifiques à la protéine de spicule ont été détectées chez 76 % des jeunes vaccinés et chez 60 % des vaccinés plus âgés. Des réponses des lymphocytes T CD4+ à biais Th-1 ont été observées dès le 15e jour après la vaccination et sont restées élevées jusqu'au 29e jour (dernier point d'évaluation dans le temps). Des réponses des lymphocytes T CD8+ spécifiques à la protéine de spicule ont été détectées chez 51 % des jeunes vaccinés et chez 36 % des vaccinés plus âgés au 15e jour après la vaccination et sont restées élevées jusqu'au 29e jour.

Réponses immunitaires anti-vectorielles
On ne sait pas exactement dans quelle mesure la population canadienne est déjà immunisée contre un vecteur vaccinal à base d'adénovirus et quel impact cela pourrait avoir sur l'innocuité et l'efficacité potentielle des vaccins à base d'adénovirus. On ne sait pas non plus dans quelle mesure l'immunisation par des vaccins à base d'adénovirus provoque des réponses immunitaires anti-vectorielles et quel impact cela pourrait avoir sur les doses de rappel homologues ou hétérologues des vaccins à base d'adénovirus. Des données probantes sur un vaccin contre la COVID-19 à vecteur viral basé sur l'adénovirus humain de type 5 (non autorisé au Canada) ont indiqué que les personnes vaccinées ayant une forte immunité préexistante au vecteur adénoviral présentaient des réponses immunitaires anti-SRAS-CoV-2 plus faibles[144]. Le vaccin contre la COVID-19 de Janssen utilise un Ad26 modifié. Janssen n'a trouvé aucune corrélation entre les réponses des anticorps neutralisants anti-Ad26 et les réponses immunitaires anti-SRAS-CoV-2. Cependant, la neutralisation n'est pas la seule réponse immunitaire anti-vectorielle qui pourrait avoir un effet sur l'immunité induite par le vaccin. On ignore encore si les réponses immunitaires au vecteur Ad26 auront un effet sur l'efficacité potentielle et réelle de ce vaccin.

Innocuité du vaccin et effets secondaires suivant l'immunisation

Les données probantes relatives à l'innocuité sont fondées sur des analyses intermédiaires de 21 895 participants (dont 7 331 avaient 60 ans ou plus) ayant reçu au moins une dose du vaccin. Un sous-ensemble sur l'innocuité comprenait 3 356 participants du groupe vacciné qui ont été suivis pour des réactions sollicitées dans les sept jours suivant la vaccination et des réactions non sollicitées dans les 28 jours suivant la vaccination. Les événements indésirables (ÉI) nécessitant des soins médicaux (ÉIM), les événements indésirables graves (ÉIG) et les ÉI ayant entraîné l'arrêt de la participation à l'étude ont été évalués chez tous les participants. Globalement, la durée médiane du suivi était de 58 jours après la vaccination.

Réactions locales sollicitées
Des ÉI sollicités au site d'injection local ont été signalés par 50,3 % des participants évalués dans les sept premiers jours suivant l'administration d'une dose de vaccin. La douleur au site d'injection a été l'ÉI local le plus fréquemment signalé (48,7 %), suivi par la chaleur (7,3 %) et l'enflure (5,3 %). Dans le groupe vacciné, la fréquence des ÉI locaux sollicités était plus faible chez les participants âgés de 60 ans et plus que chez les participants âgés entre 18 ans et plus et moins de 60 ans. La fréquence des ÉI locaux sollicités était également similaire chez les participants qui étaient séronégatifs pour le SRAS-CoV-2 au départ par rapport aux participants qui étaient

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séropositifs pour le SRAS-CoV-2 au départ (50,1 % et 54,5 %, respectivement). La plupart des réactions locales sollicitées chez les participants ayant reçu le vaccin étaient d'intensité légère ou modérée; des réactions de Stade 3 ont été déclarées par 0,7 % ou moins des participants. Aucun ÉI local sollicité de Stade 4 n'a été déclaré.

Réactions systémiques sollicitées

Des ÉI systémiques sollicités ont été signalés par 55,2 % des participants évalués dans les sept premiers jours suivant l'administration d'une dose de vaccin. Les ÉI sollicités les plus courants étaient les maux de tête (39,0 %) et la fatigue (38,3 %). Les autres ÉI systémiques sollicités fréquemment rapportés étaient des douleurs musculaires (33,2 %), des nausées (14,2 %) et une fièvre de 38,0 °C ou plus (9,0 %). Même si les ÉI étaient plus faibles chez les participants âgés de 60 ans et plus que chez les participants âgés de 18 ans et plus à moins de 60 ans, il n'y avait pas de différence pertinente au niveau clinique dans la fréquence des ÉI systémiques sollicités. Des ÉI ont été observés de façon similaire chez les participants qui étaient séronégatifs pour le SRAS-CoV-2 au départ (55,4 %) par rapport aux participants qui étaient séropositifs pour le SRAS-CoV-2 au départ (50,6 %). Dans l'ensemble, la fréquence de toutes les réactions de Stade 3 était inférieure à 2 %, et aucun ÉI systémique sollicité de Stade 4 n'a été signalé. Des antipyrétiques ont été recommandés après la vaccination pour soulager les symptômes, si nécessaire. Des analgésiques ou des antipyrétiques ont été utilisés par 26,4 % des personnes vaccinées de 18 à 59 ans et par 9,8 % des personnes vaccinées de 60 ans et plus jusqu'à sept jours après la vaccination dans le cadre de l'analyse complète. La majorité des ÉI systémiques sollicités étaient de nature transitoire et avaient une durée médiane d'un ou deux jours après la vaccination.

Événements indésirables graves non sollicités

Au cours de la période de 28 jours suivant la vaccination, 19 (0,6 %) participants ont présenté des ÉI non sollicités de Stade 3 au moins dans le groupe vacciné, contre 18 (0,6 %) participants dans le groupe placebo. Parmi ces ÉI non sollicités de Stade 3 au moins, 5 (0,1 %) ont été considérés comme étant liés au vaccin à l'étude. Il n'y a pas eu de déséquilibres évidents par classe de système d'organe (CSO). On n'a relevé aucun cas d'anaphylaxie lors des essais cliniques. Toutefois, le fabricant a annoncé avoir reçu des rapports préliminaires de deux cas de réactions allergiques sévères, dont un cas d'anaphylaxie, chez des participants ayant reçu le vaccin. Aucun détail sur les rapports n'a été fourni à ce jour.

Au total, sept participants (moins de 0,1 %) ont signalé des ÉIG qui ont été considérés par le chercheur comme étant liés au vaccin à l'étude et qui ont conduit à l'arrêt de l'étude. Voici quelques-uns de ces ÉIG :

- Syndrome de Guillain-Barré de Stade 4 chez un participant 16 jours après la vaccination. Le cas a été considéré comme étant indéterminé selon les critères liés aux effets secondaires suivant l'immunisation (ESSI) de l'OMS, toutefois, en raison de l'association temporelle étroite et de l'absence d'autres facteurs explicatifs, on a considéré qu'il était peut-être lié au vaccin, à des fins de déclaration.
- Péricardite de type 4 chez un participant environ 17 jours après la vaccination qui a entraîné une hospitalisation. Le cas a été considéré comme étant indéterminé selon les critères liés aux ESSI de l'OMS, toutefois, en raison de l'association temporelle étroite et de l'absence d'autres facteurs explicatifs, on a considéré qu'il était peut-être lié au vaccin, à des fins de déclaration.
- Radiculite brachiale de type 3 chez un participant, apparue immédiatement après la vaccination.
- Syndrome post-vaccinal de type 3 deux jours après la vaccination. Sur la base des symptômes, l'événement a été évalué comme une réactogénicité du vaccin (asthénie).

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- Hypersensibilité de type IV de classe 3 chez un participant trois jours après la vaccination. Le cas a été considéré comme étant probablement lié à la vaccination en raison de l'association temporelle étroite.
- Paralysie faciale de type 2 (paralysie de Bell) chez deux participants trois et 16 jours après la vaccination. Il a été évalué que les deux événements avaient un lien de causalité inconstant avec la vaccination, selon les critères liés aux ESSI de l'OMS.

Autres événements indésirables graves

Acouphènes
Six cas d'acouphènes ont été signalés dans le groupe vacciné et aucun dans le groupe placebo. Le chercheur a considéré que tous les cas étaient non graves, et que deux cas étaient liés. Tous les participants présentaient des affections médicales sous-jacentes (telles que des antécédents d'acouphènes et de migraines, des antécédents d'hypertension, des allergies saisonnières et une hypothyroïdie) ou prenaient des médicaments qui offraient une autre cause plus plausible pour l'événement que le vaccin.

Convulsions/crise
Quatre cas ont été signalés dans le groupe vacciné (un cas grave) et un cas (non grave) dans le groupe placebo, tous considérés comme étant non liés au vaccin de l'étude par le chercheur. Le cas grave de convulsion/crise d'épilepsie a été rapporté chez un participant ayant des antécédents d'épilepsie et de trouble obsessionnel-compulsif.

Événements thrombotiques et thromboemboliques
L'incidence globale des événements thrombotiques et thromboemboliques (artériels et veineux) était similaire dans les groupes vaccinés (n = 15, 0,1 %) et placebo (n = 10, moins de 0,1 %). Un déséquilibre numérique a été observé pour les sous-types de thrombose veineuse profonde/d'embolie pulmonaire, avec un total de neuf cas dans le groupe vacciné (quatre cas graves) et trois cas dans le groupe placebo (deux cas graves). Une occurrence de thrombose du sinus transverse est survenue le jour 21 après la vaccination chez un participant masculin âgé de 25 ans sans antécédents médicaux. Le sujet a subi également une crise épileptique déclarée comme étant une conséquence d'un saignement secondaire attribuable à une pression veineuse élevée découlant de l'obstruction du débit veineux. Deux procédures de thrombectomie ont été effectuées en raison de son état d'hypercoagulabilité. Aucune cause clairement identifiée n'a été attribuée à l'événement et l'incident a été réputé non lié au vaccin en raison de facteurs contributifs possibles (précédant l'infection et une anomalie anatomique). Un cas non grave, apparu 27 jours après la vaccination chez un participant ayant des antécédents médicaux d'obésité et de cholécystectomie, a été considéré comme étant lié au vaccin.

Thrombocytopénie thrombotique immunitaire induite par le vaccin
Ont été signalés récemment aux États-Unis de rares cas de caillots sanguins graves, notamment une thrombose des sinus veineux cérébraux, associés à une thrombocytopénie par suite de l'utilisation autorisée du vaccin contre la COVID-19 de Janssen. Ce type d'ÉI, que l'on appelle thrombocytopénie immunitaire thrombotique induite par le vaccin (TTIV), a été associé aux vaccins à vecteur viral contre la COVID-19 d'AstraZeneca et de Janssen. Le mécanisme en cause est semblable à la thrombocytopénie induite par l'héparine (TIH). Le mécanisme précis par lequel les vaccins à vecteur viral contre la maladie sont susceptibles de provoquer la TTIV fait toujours d'objet de recherche. Au 24 mai 2021, 32 cas de STT ont été confirmés sur 10,2 millions de doses de Janssen administrées aux É.-U. La majorité des cas signalés à ce jour sont survenus chez des femmes âgées de 18 à 49 ans. Toutefois, des recherches sont en cours et des cas supplémentaires peuvent être identifiés en raison d'une sensibilisation accrue et de la

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mise en évidence actuelle de la reconnaissance clinique de cet évènement. Selon les déclarations, les symptômes sont apparus entre les jours 6 et 15 après la vaccination. La recherche à ce sujet se poursuit.

Troubles démyélinisants

Au total, quatre cas de troubles démyélinisants ont été rapportés dans le groupe vacciné (deux cas de neuropathie périphérique, un cas d'hypergammaglobulinémie monoclonale bénigne, un cas de syndrome de Guillain-Barré) contre cinq cas dans le groupe placebo (deux cas de neuropathie périphérique, un syndrome de Guillain-Barré et deux pertes sensorielles).

Décès

Au total, 19 décès ont été signalés chez les participants à l'étude : 3 dans le groupe vacciné et 16 dans le groupe témoin. Dans le groupe vacciné, les causes de décès selon le terme préféré étaient l'abcès du poumon, la pneumonie non liée à la COVID-19 et un cas de cause inconnue au moment de la date limite des données. Aucun de ces décès n'a été considéré par les chercheurs comme étant lié à une quelconque intervention de l'étude.

Grossesse

Huit grossesses ont été signalées jusqu'au 22 janvier 2021 (quatre dans le groupe vacciné, quatre dans le groupe placebo). La vaccination a eu lieu dans les 30 jours suivant les dernières menstruations chez sept participantes (trois vaccins, quatre placebos), tandis que chez une participante vaccinée, la vaccination a eu lieu avant les dernières menstruations. Les ÉI non sollicités liés à la grossesse comprenaient un avortement spontané (un dans le groupe vacciné, zéro dans le groupe placebo), un avortement incomplet (zéro dans le groupe vacciné, un dans le groupe placebo), un avortement volontaire (zéro dans le groupe vacciné, deux dans le groupe placebo) et une grossesse extra-utérine (une dans le groupe vacciné, zéro dans le groupe placebo). Deux grossesses sont en cours parmi les participantes du groupe vacciné, et les issues sont inconnues à ce jour.

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ANNEXE E : FRÉQUENCE DES ÉVÈNEMENTS INDÉSIRABLES SOLLICITÉS APRÈS L'ADMINISTRATION DE VACCINS CONTRE LA COVID-19 DANS LES ESSAIS CLINIQUES

Tableau 25. Fréquence des évènements indésirables locaux sollicités dans les populations autorisées pour les vaccins à ARNm contre la COVID-19[a]

ESSI	Vaccin contre la COVID-19 de Pfizer-BioNTech								Vaccin contre la COVID-19 de Moderna			
	Adultes (≥16 ans)				Adolescents (12 -15 ans)							
	Vaccin		Placebo témoin		Vaccin		Placebo témoin		Vaccin		Placebo témoin	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Douleur au point d'injection	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Sensibilité	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Rougeur/érythème	Fréquent	Fréquent	Fréquent	Rare	Fréquent	Fréquent	Fréquent	Peu fréquent	Fréquent	Fréquent	Peu fréquent	Peu fréquent
Enflure	Fréquent	Fréquent	Rare	Rare	Fréquent	Fréquent	Fréquent	Peu fréquent	Fréquent	Très fréquent	Peu fréquent	Peu fréquent
Lymphadénopathie[b]/ Gonflement axillaire et sensibilité	NS	NS	NS	NS	NS	NS	NS	NS	Très fréquent	Très fréquent	Fréquent	Fréquent
Chaleur	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Prurit	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Induration	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

Abréviations : ESSI : effets secondaires suivant l'immunisation; menACWY : vaccin méningococcique quadrivalent; NS : non sollicité

[a] Très fréquent = se produit chez 10 % ou plus des personnes vaccinées, Fréquent = se produit chez 1 à moins de 10 % des personnes vaccinées, Peu fréquent = se produit chez 0,1 % à moins de 1 % des personnes vaccinées

[b] La lymphadénopathie n'était pas un événement indésirable sollicité pour le vaccin contre la COVID-19 de Pfizer-BioNTech et a été signalée comme un événement indésirable non sollicité. Veuillez consulter l'Annexe A pour plus de détails.

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Tableau 26. Fréquence des évènements indésirables locaux sollicités dans les populations autorisées pour les vaccins à vecteur viral contre la COVID-19[a]

ESSI	Vaccin contre la COVID-19 d'AstraZeneca				Vaccin contre la COVID-19 de Janssen[b]	
	Vaccin		MenACWY témoin		Vaccin	Témoin placebo
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Douleur au point d'injection	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Sensibilité	Très fréquent	Très fréquent	Très fréquent	Très fréquent	NS	NS
Rougeur/érythème	Très fréquent	Fréquent	Fréquent	Peu fréquent	Fréquent	Fréquent
Enflure	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent
Lymphadénopathie[c]/ Gonflement axillaire et sensibilité	NS	NS	NS	NS	NS	NS
Chaleur	Très fréquent	Fréquent	Très fréquent	Fréquent	NS	NS
Prurit	Très fréquent	Fréquent	Fréquent	Fréquent	NS	NS
Induration	Fréquent	Fréquent	Fréquent	Fréquent	NS	NS

Abréviations : ESSI : effets secondaires suivant l'immunisation; menACWY : vaccin méningococcique quadrivalent; NS : non sollicité

[a] Très fréquent = se produit chez 10 % ou plus des personnes vaccinées, Fréquent = se produit chez 1 à moins de 10 % des personnes vaccinées, Peu fréquent = se produit chez 0,1 % à moins de 1 % des personnes vaccinées

[b] Vaccin à dose unique (deuxième dose non applicable)

[c] La lymphadénopathie n'était pas un évènement indésirable sollicité pour le vaccin contre la COVID-19 d'AstraZeneca et a été signalée comme un événement indésirable non sollicité. Veuillez consulter l'Annexe C pour plus de détails.

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Tableau 27. Fréquence des évènements indésirables systémiques sollicités dans les populations autorisées pour les vaccins à ARNm contre la COVID-19[a]

ESSI	Vaccin contre la COVID-19 de Pfizer-BioNTech								Vaccin contre la COVID-19 de Moderna			
	Adultes (≥16 ans)				Adolescents (12 -15 ans)							
	Vaccin		Placebo témoin		Vaccin		Placebo témoin		Vaccin		Placebo témoin	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Céphalées	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Douleurs musculaires	Très fréquent	Très fréquent	Fréquent	Fréquent	Très fréquent	Très fréquent	Très fréquent	Fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Frissons	Très fréquent	Très fréquent	Fréquent	Fréquent	Très fréquent	Très fréquent	Fréquent	Fréquent	Fréquent	Très fréquent	Fréquent	Fréquent
Douleurs articulaires	Fréquent	Très fréquent	Fréquent	Fréquent	Fréquent	Très fréquent	Fréquent	Fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Fièvre[b]	Fréquent	Très fréquent	Peu fréquent	Peu fréquent	Très fréquent	Très fréquent	Fréquent	Peu fréquent	Peu fréquent	Très fréquent	Peu fréquent	Peu fréquent
Fébrilité[b]	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
Diarrhée	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent	Fréquent	NS	NS	NS	NS
Nausées et/ou vomissements[c]	Peu fréquent	Fréquent	Peu fréquent	Peu fréquent	Fréquent	Fréquent	Peu fréquent	Fréquent	Fréquent	Très fréquent	Fréquent	Fréquent

Abréviations : ESSI : effets secondaires suivant l'immunisation; menACWY : vaccin méningococcique quadrivalent; NS : non sollicité

[a] Très fréquent = se produit chez 10 % ou plus des personnes vaccinées, Fréquent = se produit chez 1 à moins de 10 % des personnes vaccinées, Peu fréquent = se produit chez 0,1 % à moins de 1 % des personnes vaccinées

[b] La fièvre était la déclaration objective d'une température ≥ 38 °C/100,4 °F. La fébrilité était un sentiment subjectif et autodéclaré d'avoir de la fièvre.

[c] Si deux éléments sont déclarés, le premier reflète la nausée et le deuxième reflète la fréquence de vomissements.

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Tableau 28. Fréquence des évènements indésirables systémiques sollicités dans les populations autorisées pour les vaccins à vecteur viral contre la COVID-19[a]

ESSI	Vaccin contre la COVID-19 d'AstraZeneca				Vaccin contre la COVID-19 de Janssen[b]	
	Vaccin		MenACWY témoin		Vaccin	Placebo témoin
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Fatigue	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Céphalées	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Douleurs musculaires	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent	Très fréquent
Frissons	Très fréquent	Fréquent	Fréquent	Fréquent	NS	NS
Douleurs articulaires	Très fréquent	Très fréquent	Fréquent	Fréquent	NS	NS
Fièvre[c]	Fréquent	Peu fréquent	Peu fréquent	Peu fréquent	Fréquent	Peu fréquent
Fébrilité[c]	Très fréquent	Fréquent	Fréquent	Fréquent	NS	NS
Diarrhée	NS	NS	NS	NS	NS	NS
Nausées et/ou vomissements[c]	Très fréquent/ Fréquent	Fréquent/ Peu fréquent	Très fréquent/ Peu fréquent	Fréquent/ Peu fréquent	Très fréquent	Fréquent

Abréviations : ESSI : effets secondaires suivant l'immunisation; menACWY : vaccin méningococcique quadrivalent; NS : non sollicité

[a] Très fréquent = se produit chez 10 % ou plus des personnes vaccinées, Fréquent = se produit chez 1 à moins de 10 % des personnes vaccinées, Peu fréquent = se produit chez 0,1 % à moins de 1 % des personnes vaccinées

[b] Vaccin à dose unique (deuxième dose non applicable)

[c] La fièvre était la déclaration objective d'une température ≥ 38 °C/100,4 °F. La fébrilité était un sentiment subjectif et autodéclaré d'avoir de la fièvre.

[d] Si deux éléments sont déclarés, le premier reflète la nausée et le deuxième reflète la fréquence de vomissements.

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ANNEXE F : GROSSESSE, ALLAITEMENT ET REGISTRES DE VACCINATION CONTRE LA COVID-19

Il existe un registre canadien de vaccination contre la COVID-19 pour les personnes enceintes ou qui allaitent (en anglais seulement) :

- Registre canadien de vaccination contre la COVID-19 pour les personnes enceintes ou qui allaitent

Tableau 29 : Information sur le registre pour personnes enceintes selon le produit de vaccination

Produit de vaccination	Information sur le registre
Vaccin contre la COVID-19 de Pfizer-BioNTech	Pfizer ne dispose pas de registre d'exposition pour personnes enceintes. Celles qui ont reçu le vaccin contre la COVID-19 de Pfizer ainsi que les fournisseurs de soins de santé sont incités à déclarer au fabricant toute exposition au vaccin contre la COVID-19 durant la grossesse et l'allaitement (1-866-723-7111).
Vaccin contre la COVID-19 de Moderna	Il existe un registre d'exposition qui permet de surveiller toute issue chez les personnes enceintes exposées au vaccin contre la COVID-19 de Moderna. Celles qui reçoivent ce vaccin durant la grossesse sont incitées à s'inscrire au registre en appelant le 1-866-MODERNA (1-866-663-3762).
Vaccin contre la COVID-19 d'AstraZeneca	Il existe un registre d'exposition qui permet de surveiller toute issue chez les personnes enceintes exposées au vaccin contre la COVID-19 d'AstraZeneca. Celles qui reçoivent ce vaccin durant la grossesse sont incitées à s'inscrire au registre en consultant l'adresse https://c-viper.pregistry.com ou en appelant le 1-800-616-3791.
Vaccin contre la COVID-19 de Janssen	Il existe un registre d'exposition qui permet de surveiller toute issue chez les personnes enceintes exposées au vaccin contre la COVID-19 de Janssen. Celles qui reçoivent ce vaccin durant la grossesse sont incitées à s'inscrire au registre en consultant l'adresse https://c-viper.pregistry.com

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Agence de la santé publique du Canada | Public Health Agency of Canada

Canada

RÉSUMÉ DE LA DÉCLARATION DU COMITÉ CONSULTATIF NATIONAL DE L'IMMUNISATION (CCNI) – MISES À JOUR DU 2 JUILLET 2021

CONFIDENTIEL – NE PAS DIFFUSER

2 JUILLET 2021

PROTÉGER LES CANADIENS ET LES AIDER À AMÉLIORER LEUR SANTÉ

Page 1 de 1,581
A2021000080

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VACCINS À ARN MESSAGER CONTRE LA COVID-19 ET MYOCARDITE

- Le 2 juillet 2021, l'Agence de la santé publique du Canada a publié une mise à jour des conseils du Comité consultatif national de l'immunisation (CCNI) sur l'utilisation des vaccins à ARNm contre la COVID-19. Ces recommandations sont fondées sur les preuves scientifiques actuelles et l'opinion des experts du CCNI.

- Le 30 juin 2021, Santé Canada a mis à jour les monographies, les documents qui fournissent des informations aux prestataires de soins de santé sur l'utilisation des vaccins, pour des vaccins à ARNm contre la COVID-19 (Pfizer-BioNTech et Moderna) afin d'inclure les très rares rapports de myocardite (inflammation du muscle cardiaque) et de péricardite (inflammation du tissu entourant le cœur) survenus après la vaccination.

- À la lumière de ces changements, le CCNI présente des conseils actualisés sur les deuxièmes doses pour les personnes ayant subi une myocardite ou une péricardite après avoir reçu une première dose d'un vaccin à ARNm.

- Le CCNI continue de recommander vivement de proposer une série complète d'un vaccin à ARNm à toutes les personnes admissibles qui ne présentent pas de contre-indications, y compris celles âgées de 12 ans et plus. Le vaccin de Pfizer-BioNTech est approuvée chez les sujets âgés de 12 ans et plus et celle du vaccin de Moderna est approuvée chez les personnes âgées de 18 ans et plus.

Le CCNI recommande également ce qui suit :

- Consentement éclairé pour les personnes recevant un vaccin à ARNm doit inclure une discussion sur le risque très rare de myocardite ou de péricardite après l'immunisation.

- Par mesure de précaution, le CCNI recommande aux personnes ayant souffert d'une myocardite ou d'une péricardite après une première dose d'un vaccin à ARNm d'attendre que de plus amples informations soient disponibles avant de recevoir leur deuxième dose.

Vous pouvez consulter la déclaration complète sur le site Recommandations sur l'utilisation du ou des vaccins contre la COVID-19.

CE QUE VOUS DEVEZ SAVOIR

La myocardite est une inflammation du muscle cardiaque et la péricardite, une inflammation de la membrane qui entoure le cœur. La myocardite et la péricardite

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peuvent avoir de nombreuses causes, notamment des infections virales. Elles peuvent également se produire comme une complication chez les personnes infectées par le SRAS-CoV-2, le virus COVID-19.

- Un petit nombre de cas de myocardite ou de péricardite ont été signalés au Canada et à l'étranger après l'immunisation avec des vaccins à ARNm contre la COVID-19. À l'échelle internationale, les cas ont été signalés plus fréquemment chez les adolescents et les jeunes adultes de moins de 30 ans, plus souvent de sexe masculin que de sexe féminin et plus souvent après une deuxième dose. La majorité des cas ont été bénins et les malades ont récupéré rapidement.

- Le CCNI continue de recommander vivement de proposer une série complète avec un vaccin à ARNm à tous les individus admissibles, y compris ceux âgés de 12 ans et plus. Les vaccins à ARNm contre la COVID-19 offrent une très bonne protection contre l'infection par le SRAS-CoV-2 et la maladie symptomatique de la COVID-19, y compris la maladie grave, l'hospitalisation et le décès.

- Les personnes à qui l'on propose un vaccin à ARNm contre la COVID-19 doivent être informés du risque très rare de myocardite ou de péricardite après l'immunisation et doivent être invités à consulter immédiatement un médecin s'ils présentent des symptômes, lesquels peuvent inclure des douleurs thoraciques, un essoufflement ou la sensation d'un rythme cardiaque rapide ou fort ou de palpitations. Les cas surviennent généralement dans une semaine après la réception d'une dose de vaccin à ARNm, plus fréquemment après une deuxième dose. Tous les cas potentiels doivent faire l'objet d'une évaluation médicale, quel que soit le délai entre la vaccination et l'apparition des symptômes.

- Par mesure de précaution, le CCNI recommande aux personnes ayant souffert d'une myocardite ou d'une péricardite après une première dose d'un vaccin à ARNm contre la COVID-19 d'attendre que de plus amples informations soient disponibles avant de recevoir leur deuxième dose.

- Les données probantes sur ce signal de sécurité et les enquêtes sur une association entre la myocardite et/ou péricardite et les vaccins à ARNm contre la COVID-19 continuent d'évoluer. Le CCNI continuera à surveiller les données probantes et mettra à jour ses recommandations si nécessaire.

CITATIONS

« Nous continuons à voir des risques liés à la COVID-19 dans nos collectivités, et bien que les reportages de vaccination des adultes augmentent chaque jour, il y a eu des éclosions récentes chez les adolescents au Canada et à l'étranger. Il est important que les adolescents continuent à se faire vacciner, en particulier dans le contexte de l'émergence du variant Delta au Canada. »

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« Nous suivons de près l'évolution de la situation des rares cas de myocardite ou de péricardite survenant après l'administration d'un vaccin à ARNm chez les jeunes. Le CCNI est encouragé par le fait que le tableau clinique semble léger et se résout rapidement. Les avantages du programme d'immunisation contre la COVID-19 continuent à l'emporter sur le risque relativement faible pour toutes personnes, y compris les adolescents. Il sera important que le consentement éclairé comprenne une discussion sur les éléments à surveiller après la vaccination et sur la nécessité de consulter un médecin si des symptômes apparaissent. Par mesure de précaution, toute personne qui présente une myocardite ou une péricardite après la première dose doit attendre que nous en sachions plus avant de recevoir une seconde dose. »

- – Dre Shelley Deeks, présidente du CCNI

« Un petit nombre de cas de myocardite et de péricardite ont été signalés au Canada après la vaccination. Les données probantes évoluent et les enquêtes canadiennes et internationales sur une association entre la myocardite/péricardite et les vaccins à ARNm se poursuivent. Je tiens à faire savoir aux Canadiens que les avantages des vaccins à ARNm contre la COVID-19 continuent de l'emporter sur leurs risques potentiels. Il est important que chacun reçoive sa deuxième dose de vaccin afin de bénéficier de la meilleure protection possible. Le gouvernement du Canada encourage les gens à se faire vacciner et à compléter leur série de vaccins dès qu'ils sont admissibles. »

- Dre Theresa Tam, administratrice en chef de la santé publique

PROCHAIN ORDRE DU JOUR DU CCNI :

Le CCNI continue à examiner activement les preuves émergentes sur les vaccins contre la COVID-19. Les recommandations à venir pourront inclure de nouveaux conseils sur les points suivants :

- Recommandation sur l'utilisation du vaccin contre la COVID-19 à ARNm Moderna chez les adolescents (en attente de décision réglementaire par Santé Canada)
- Nombre optimal de doses pour les personnes ayant déjà été infectées par le SRAS-CoV-2 (prévu pour l'été 2021)
- Conseils aux personnes ayant reçu une série partielle ou complète de vaccins contre la COVID-19 avec un vaccin non autorisé au Canada (prévu pour l'été 2021)

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From: Kropp2, Rhonda (PHAC/ASPC)
Sent: 2020-08-10 5:47 PM
To: Tam, Dr Theresa (PHAC/ASPC)
Subject: FW: MINDM Background Doc: Vaccine compensation
Attachments: MINDM - Vaccine Injury Compensation 2020-08-10 1730.docx

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From: Kropp2, Rhonda (PHAC/ASPC)
Sent: 2020-08-10 5:38 PM
To: Namiesniowski, Tina (PHAC/ASPC) ; Slowey2, Charles (PHAC/ASPC)
Cc: Charos, Gina (PHAC/ASPC) ; Dickson, Samantha M (HC/SC)
Subject: MINDM Background Doc: Vaccine compensation

Hello to you both,
As you know, on MinDM tomorrow, there is an item on vaccines that covers: [redacted] (Sam leading), vaccine procurement (Roman leading) and vaccine compensation (me).
Not sure about process, but attached is the proposed backgrounder for the vaccine compensation component of that agenda item.
Charles, should I be sending this to Kendal directly or are you guys sending as a package?
Thanks Gina for your teams' rapid work on this....much appreciated.
Rhonda

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Backgrounder – National Vaccine Injury Compensation Program

Context

- As is the case with all vaccines, a small number of Canadians will experience an adverse event following immunization (AEFI) related to a new COVID-19 vaccine. AEFI's can range from mild (e.g. pain at the injection site, swelling, fever) to more severe (e.g. anaphylaxis and in rare instances death.)

- With the exception of Canada and Russia, most Western countries have established vaccine injury compensation programs that provide timely compensation to victims based on explicit criteria and without the need for expensive litigation. (Quebec established a no-fault plan in 1988).

- While the nature, scope and governance of these plans vary by jurisdiction, ethical factors have been the primary drivers. The core argument for no-fault vaccine injury compensation hinges on the ethical principal of reciprocity.

- Notwithstanding that COVID-19 pandemic vaccines contracts will have indemnification clauses, there is growing pressure from the sector for Canada to establish a no-fault national vaccine injury compensation program in advance of COVID-19 vaccine deployment.

- The issue was championed by the Council of Deputy Ministers of Health (1987); endorsed again by all jurisdictions as a priority for a renewed National Immunization Strategy (NIS) in 2013 and most recently discussed by the Public Health Network-Council (2015) in the context of their endorsement of the NIS renewal plan.

- While public health in Canada is an area of shared jurisdiction, the GoC role does not extend to making decisions about which vaccines to include in provincial and territorial (P/T) health plans or the actual delivery of vaccines to the public. Although Canada's National Advisory Committee on Immunization (NACI) provides guidance on vaccine use, P/Ts are primarily responsible for vaccinations and have final say on how, when and to whom they will be administered.

- A precondition for any successful regime is the ability to track who is getting what vaccine, when and how. However, each P/T tracks and reports vaccine coverage data differently and federal, provincial and territorial (F/P/T) data-sharing agreements in this domain are complex, cumbersome and uneven.

Next Steps

- PHAC is undertaking a rapid analysis to explore options for such a regime in Canada. Aim will be to:
  - Summarize the regimes in other countries, including their cost, model and pubic acceptance where known
  - Provide a recommendation for or against a National Vaccine Injury Compensation Program, and if for, provide options for program design, scope and timing.

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- Provide recommendation regarding infrastructure needed for such a regime to be successful (for example, data collection/registries for COVID vaccination, comprehensive vaccine deployment strategy).

Drawing from previous plans and emerging best practices, should the GoC wish to proceed with an injury compensation plan, the following options, among others, may be considered.

- A cost share model
- An arms length entity
- An in-house federal program

Considerations Moving Forward

- **Defining federal position prior to P/T Engagement**: GoC would need to define what type of data it would require from P/Ts for a national compensation program. The GoC position regarding compensating Quebec for its established plan would need to be established.

- **Authorities:** GoC would require policy cover for assisting P/Ts with exploring options for each jurisdiction implementing their own system. However, compensation for vaccine injury has not been available through the legal system in Canada, therefore a change in policy and legislation would be required should a pan-Canadian no-fault vaccine injury compensation program be established.

- **Communication:** From a communications perspective, the optics of establishing a national vaccine injury compensation program during a pandemic may result in giving vaccine hesitant Canadians further pause when considering receiving a COVID-19 vaccine (i.e. "are there more anticipated risks associated with COVID-19 vaccine(s)?"). A strong communication plan would be needed to accompany the program to highlight the public good intent of the initiative.

- **Guiding Principles**: If there is a decision to proceed, an early decision on guiding principles (e.g. fairly compensate anyone injured by a vaccine recommended by the GoC and administered consistent with NACI recommendations, or only compensate for vaccine approved during the emergency release of a vaccine during an outbreak or pandemic?).

- **Scope:** Will need to determine if there is a desire to proceed with a COVID vaccine injury compensation program after which lessons learned would be used to broaden. Within a "national" system, a statute of limitations for filing claims (e.g. x years from injury onset) will need to be established, as will the scope of injuries that would be covered; GoC will need to determine what evidence will be needed to substantiate a claim, and; a mechanism to estimate measurable uninsured damages and costs to injuries will need to be established.

- **Funding**: Whether the system would be federally financed or cost-shared; how the system would be financed (e.g. excise taxes on vaccines versus public sector funding).

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From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2021-06-30 9:04 AM
Cc: HC.F Comms_Coordination F.SC; van Oosten, Marianne (HC/SC)
Subject: FYI: PA | mRNA vaccines and myocarditis/pericarditis
Attachments: HPFB_PA_mRNA label_AEFIs_2021-06-29_1745_FINAL_FR.docx; HPFB_PA_mRNA label_AEFIs_2021-06-29_1745_FINAL_EN.docx

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Good morning,

Please see attached an advisory on mRNA vaccines and myocarditis/pericarditis, for information. We aim to post at 2pm today.

Merci!
Alexandre

Issue:
Health Canada has updated the product monographs (labels) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to describe very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.

Approvals:
Megan Bettle, DG, COVID-19 Regulatory Response Team (June 28, 2021)
Stephanie Hunt, A/DG, BRDD (June 28, 2021)
Melissa Hunt, Dir, Marketed Health Products Directorate, HPFB, HC (June 28, 2021)
Kelly Robinson, DG, Marketed Health Products Directorate, HPFB, HC (June 28, 2021)
Susanna Ogunnaike-Cooke, A/DG, CIRID, PHAC (FYI)
Anne-Marie Ugnat, DG, PHAC (FYI)
Erika Demaine, A/Comms Executive, Vaccine Comms (FYI)
Marilyne Nahum, A/Comms Executive, (June 28, 2021)
Cathy Lafkas, Director, Strategic Communications (June 28, 2021 - June 28, 2021)
Gillian Badger for Heather Magee, Executive Director, Vaccine Comms, CPAB (FYI)
Jon Ward, CPAB DG (June 28, 2021 - June 28, 2021)
Cathy Allison, DG, Vaccines (FYI)
Kaili Levesque, VP, VRAT (FYI)
Pam Aung-Thin, a/ADM, CPAB (June 28, 2021 - June 29, 2021)
Supriya Sharma, ADM, HPFB (June 28, 2021 - June 29, 2021)
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Pres/CPHO (FYI)
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(HC/SC) ; Carbonneau, Pascale (HC/SC) ; Emon, Mary (HC/SC) ; Zed, Kathryn (HC/SC) ; Mursell, Lissa (HC/SC) ; Clarke, Andrea (HC/SC) ; Nayeri, Gita (HC/SC) ; Roy, Marc-André (HC/SC) ; Bartman, Christopher (HC/SC) ; Larose, Melanie (HC/SC) ; Cropley, Julia (HC/SC) ; HC.F SCD DGO / BDG DCS F.SC

Alexandre Richer-Brulé
(he / him | il / lui)

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***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 17 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre comms_coordination@canada.ca en cc.*

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Advisory

Health Canada updates Pfizer-BioNTech and Moderna COVID-19 vaccine labels to include information on myocarditis and pericarditis

June 30, 2021
For immediate release

Summary
Product: Pfizer-BioNTech and Moderna COVID-19 vaccines
Issue: Health Canada has updated the product monographs (labels) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to describe very rare reports of myocarditis and pericarditis following vaccination.
What to do: Seek medical attention immediately if you experience any of the following symptoms within several days of vaccination: chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart.

Issue

Health Canada has updated the product monographs (labels) for the Pfizer-BioNTech and Moderna COVID-19 vaccines to describe very rare reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination.

Cases of myocarditis and/or pericarditis following immunization with COVID-19 vaccines have been reported in a small number of people in Canada and internationally. These reports are very rare. Health Canada and other international regulators are continuing to investigate the potential relationship between COVID-19 vaccines and these rare events. Most reported cases to date have followed vaccination with an mRNA vaccine (Pfizer-BioNTech and Moderna) and, based on an analysis of international cases, have occurred more often after the second dose and in younger male adults and adolescents. The Canadian evidence is expected to evolve as more people in these populations are vaccinated. Available short-term follow-up data show that these events were typically mild and treatable; however, information on long-term outcomes is not yet available.

Myocarditis is an inflammation of the heart muscle, while pericarditis is an inflammation of the lining around the heart. Both conditions can result from an infection (including COVID-19), exposure to a toxic substance or radiation, or other health events. Symptoms can include chest pain, shortness of breath, or palpitations (feelings of having a fast-beating, fluttering or pounding heart). In many cases, these conditions are mild and require little to no treatment. However, more severe cases can lead to heart muscle damage.

Health Canada has updated the product labels for the Pfizer-BioNTech and Moderna COVID-19 vaccines to inform Canadians and healthcare professionals of these possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention following vaccination.

Health Canada will continue to work with manufacturers, as well as domestic and international partners, to gain a better understanding of the relationship between COVID-19 vaccines and these events. In addition, Health Canada and the Public Health Agency of Canada will continue to monitor Canadian and international reports of myocarditis and/or pericarditis, particularly as

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more adolescents and young adults are vaccinated and more second doses are administered. The Department will take appropriate action will be taken if any new safety issues are identified.

Health Canada reassures Canadians that COVID-19 vaccines continue to be safe and effective at protecting them against COVID-19. The benefits of COVID-19 vaccines continue to outweigh their potential risks, as scientific evidence shows that they reduce deaths and hospitalizations due to COVID-19. The Government of Canada encourages people to get vaccinated and to complete their vaccine series as soon as they are eligible.

For further information on COVID-19 vaccines in Canada, please visit Health Canada's COVID-19 vaccines and treatments portal.

What consumers should do

If you have received the Pfizer-BioNTech and Moderna COVID-19 vaccines:
Seek medical attention immediately if you experience any of the following symptoms within several days of vaccination:

- chest pain
- shortness of breath
- feelings of having a fast-beating, fluttering or pounding heart.

Report any adverse events after immunization to your healthcare professional.

What health professionals should do

- Be alert to the signs and symptoms of myocarditis and pericarditis when individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms following immunization with a COVID-19 vaccine. This could allow for early diagnosis and treatment. Cardiology consultation for management and follow-up should be considered.
- When deciding whether to administer the Pfizer-BioNTech or Moderna COVID-19 vaccine to an individual with a history of myocarditis or pericarditis, consider the individual's clinical circumstances.
- Report any event potentially related to a vaccine. To report a side effect to Health Canada contact your local health unit or visit Health Canada's Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax.

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Media Enquiries
Health Canada
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hc.media.sc@canada.ca

Public Enquiries
(613) 957-2991
1-866 225-0709

Également disponible en français

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Avis

Santé Canada met à jour les étiquettes des vaccins contre la COVID-19 de Pfizer-BioNTech et de Moderna pour y inclure des renseignements sur la myocardite et la péricardite

30 juin 2021
Pour diffusion immédiate

Sommaire
Produit : Vaccins de Pfizer-BioNTech et de Moderna contre la COVID-19
Question : Santé Canada a mis à jour les monographies (étiquettes) des vaccins contre la COVID-19 de Pfizer-BioNTech et de Moderna afin de décrire les très rares cas de myocardite et de péricardite signalés après la vaccination.
Ce qu'il faut faire : Consultez immédiatement un médecin si vous présentez l'un des symptômes suivants dans les jours qui suivent la vaccination : douleur thoracique, essoufflement, sensation de battements de cœur rapides, de palpitations ou de forts battements de cœur.

Question

Santé Canada a mis à jour les monographies (étiquettes) des vaccins contre la COVID-19 de Pfizer-BioNTech et de Moderna afin de décrire les très rares cas de myocardite et de péricardite signalés après la vaccination.

Des cas de myocardite et de péricardite après l'immunisation par les vaccins contre la COVID-19 ont été signalés chez un faible nombre de personnes au Canada et à l'étranger. Ces rapports sont très rares. Santé Canada et d'autres organismes de réglementation internationaux continuent d'enquêter sur la relation éventuelle entre les vaccins contre la COVID-19 et ces événements rares. La plupart des cas signalés à ce jour ont reçu le vaccin à ARNm (Pfizer-BioNTech et Moderna) et, selon une analyse des cas à l'étranger, sont survenus plus souvent après la deuxième dose et chez des adultes et des adolescents masculins plus jeunes. Les données canadiennes devraient évoluer au fur et à mesure qu'un plus grand nombre de personnes de ces populations seront vaccinées. Les données disponibles sur le suivi à court terme montrent que ces événements étaient généralement légers et traitables; toutefois, on ne dispose pas encore de renseignements sur les résultats à long terme.

La myocardite est une inflammation du muscle cardiaque, tandis que la péricardite est une inflammation de l'enveloppe du cœur. Ces deux affections peuvent résulter d'une infection (y compris de la COVID-19), d'une exposition à une substance toxique ou à des radiations, ou d'autres problèmes de santé. Les symptômes peuvent inclure des douleurs thoraciques, un essoufflement ou des battements de cœur incommodes (sensation de battements rapides, de palpitations ou de forts battements de cœur). Dans de nombreux cas, ces affections sont bénignes et ne nécessitent que peu ou pas de traitement. Toutefois, les cas plus graves peuvent entraîner des lésions du muscle cardiaque.

Santé Canada a mis à jour les étiquettes des vaccins contre la COVID-19 de Pfizer-BioNTech et de Moderna afin d'informer les Canadiens et les professionnels de la santé de ces effets secondaires possibles, de fournir des renseignements sur les signes et les symptômes et d'indiquer quand il faut consulter rapidement un médecin après la vaccination.

Santé Canada continuera de travailler avec les fabricants et avec ses partenaires nationaux et internationaux afin de mieux comprendre le lien entre les vaccins contre la COVID-19 et ces événements. En outre, Santé Canada et l'Agence de la santé publique du Canada continueront

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de surveiller les rapports nationaux et internationaux concernant la myocardite et la péricardite, en particulier parce que de plus en plus d'adolescents et de jeunes adultes sont vaccinés et que davantage de deuxièmes doses sont administrées. Le Ministère prendra les mesures appropriées si de nouveaux problèmes de sécurité sont relevés.

Santé Canada rassure les Canadiens : les vaccins contre la COVID-19 continuent d'être sûrs et efficaces pour les protéger contre la COVID-19. Les avantages des vaccins contre la COVID-19 continuent de l'emporter sur leurs risques éventuels, car les preuves scientifiques montrent qu'ils réduisent les décès et les hospitalisations dus à la COVID-19. Le gouvernement du Canada encourage les gens à se faire vacciner et à compléter leur série de vaccins dès qu'ils sont admissibles.

Pour obtenir de plus amples renseignements sur les vaccins contre la COVID-19 au Canada, veuillez consulter le portail de Santé Canada sur les vaccins et les traitements contre la COVID-19.

Instructions à l'intention des consommateurs

Si vous avez reçu un des vaccins contre la COVID-19 de Pfizer-BioNTech et de Moderna : consultez immédiatement un médecin si vous présentez l'un des symptômes suivants dans les jours suivant la vaccination :

- douleur thoracique;
- essoufflement;
- sensation de battements de cœur rapides, de palpitations ou de forts battements de cœur.

Signalez tout effet secondaire après la vaccination à votre professionnel de la santé.

Instructions à l'intention des professionnels de la santé

- Surveillez les signes et les symptômes de la myocardite et de la péricardite lorsque des personnes disent ressentir des douleurs thoraciques, un essoufflement, des palpitations ou présentent d'autres signes ou symptômes après avoir reçu un vaccin contre la COVID-19. Cela pourrait permettre un diagnostic et un traitement précoces. Une consultation en cardiologie pour la prise en charge et le suivi devrait être envisagée.
- Au moment de décider d'administrer le vaccin contre la COVID-19 de Pfizer-BioNTech ou de Moderna à une personne ayant des antécédents de myocardite ou de péricardite, il faut tenir compte des circonstances cliniques de la personne.
- Signalez tout événement qui pourrait être lié à un des vaccins. Pour signaler un effet secondaire à Santé Canada, communiquez avec votre bureau de santé local ou visitez la page Web de Santé Canada sur le signalement des effets secondaires pour savoir comment faire une déclaration en ligne, par la poste ou par télécopieur.

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Demandes de renseignements des médias
Santé Canada
613-957-2983
hc.media.sc@canada.ca

Demandes de renseignements du public
613-957-2991

Also available in English

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866-225-0709

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From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2021-05-28 9:27 AM
To: Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Watkins2, Kerri (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Wright, Katharine (PHAC/ASPC); Maika, Christine (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Roussy, Eve (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC); Oliver, Kathleen (PHAC/ASPC); Lachapelle, Dominic (PHAC/ASPC); OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC)
Cc: Yu, Sarah C (HC/SC); Marchand, Katrina (HC/SC); Demaine, Erika (HC/SC); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); COVIDvaccineComms / VaccincontrelaCOVIDcommunications (HC/SC); Demaine, Erika (HC/SC); Badger, Gillian (HC/SC); Ramkissoon2, Kevin (HC/SC); HC.F Comms_Coordination F.SC; Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); ADMO CPAB / BSMA DGCAP (HC/SC); HC.F CPAB ADMO Advisors F.SC; HC.F CPHO Coordination / Coordination ACSP F.SC; Cropley, Julia (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Aylward, Brett (HC/SC); Ouellette, Francis (HC/SC)
Subject: For CPHO/President Approval: NR, ML, Web, CPHO Tweets | Vaccine Injury Support Program (VISP)
Attachments: PHAC_MLQA VISP_ Program launch_2021-05-25_1230.docx; PHAC_NR_Vaccine Injury Support Program 2021_05_25_2000.docx; WEB VISP_Program Launch _ 2021_05_25_2000.docx; PHAC_SM_VISP Program launch_2021_05_26_1328.docx

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Good morning,

Please see attached comms products and web content, as well as the below CPHO tweet, for the Vaccine Injury Support Program (VISP) for your approval by 4pm today.

The SM plan is attached for your information.

Thank you,
Amanda

CPHO Tweet for Approval:

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Date	Post Timing (if specific)	English Message
June 1, 2021 (TBC)		Today the Public Health Agency of Canada launched a Vaccine Injury Support Program that will support people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine. For more information, visit: https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Context: On June 1 (TBC), the Public Health Agency of Canada (PHAC) will announce the launch of the Vaccine Injury Support Program, the third party administrator (Raymond Chabot Grant Thornton) and their readiness to accept claims from people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada.

Approvals:
Stephanie Parisien, Director, SPPB (May 18, 2021)
Stephen Bent, VISP, DG (May 20, 2021)
Chief Operations (May 20, 2021 - FYI)
HPOC EM (May 20, 2021 - FYI)
Erika Demaine, A/Comms Executive, vaccine Comms (May 20, 2021)
Heather Magee, Executive Director, CPAB PCRT (May 25 & 26, 2021)
Cathy Lafkas, Director, Strategic Communications (FYI)
Cathy Allison, DG, CPAB vaccine communications (May 25, 2021)
Jon Ward for Sara Mackenzie, DG, CPAB (FYI)
Kim Elmslie, VP (May 27, 2021)
Cathy Allison for Pam Aung-Thin, a/ADM, CPAB (FYI – approved as DG)
Dr. Njoo, DCPHO (FYI)
Kaili Levesque, ADM, COVID-19 Secretariat (FYI)
Pierre Sabourin, ADM, HPFB (FYI)
President/CPHO (pending)
DMO (pending)
MO (FYI)/PCO (pending)

Amanda Ing
(she | elle)

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***Please note** emails to Comms_Coordination@canada.ca are monitored from 8am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*

***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 8 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Public Health Agency of Canada | Agence de la santé publique du Canada

Updated – May 25, 2021

Media Lines

Vaccine Injury Support Program

Issue: In December 2020, Prime Minister Trudeau announced that the Public Health Agency of Canada (PHAC) would establish a pan-Canadian no-fault Vaccine Injury Support Program (VISP), in consultation with provinces and territories. The program is now operational and ready to accept claims.

Note: Timing of announcement on the launch of the VISP to occur on or after June 1, 2021. Please refer to AEFI and VITT media lines packages for latest messaging and statistics.

Key messages:

- Vaccination is one of the most effective ways to protect yourself, your family and community from getting and spreading serious diseases.
- All immunization programs are based on the principle of reciprocity. The Government of Canada is committed to ensuring that Canadians who support public health by being vaccinated are supported should they experience a serious and permanent injury as a result of vaccination.
- The Public Health Agency of Canada (PHAC) has established a pan-Canadian no-fault Vaccine Injury Support Program (VISP), in consultation with the provinces and territories.
- After an open solicitation and thorough review, RCGT Consulting was selected to be the third-party administer of the VISP.
- The VISP is now accepting claims. People in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada, on or after December 8, 2020 can submit a claim requesting financial support. This includes claims for death benefits.
- The province of Québec will continue to administer its existing provincial program for people vaccinated in Québec. Individuals vaccinated in all other provinces and territories will receive coverage under the pan-Canadian program.
- More information on how to file a claim is available on RCGT Consulting's website: at vaccineinjurysupport.ca.

If pressed on timing of program launch:
The need for a vaccine injury support program has been previously identified as a gap in Canada's immunization system and recognized as an area of importance by the Government of Canada, the provinces and the territories. By implementing this Program, Canada is now in line with a growing number of countries that have such programs in place, including all G7 counterparts.

If pressed on FPT discussions:
Immunization is a shared responsibility among the federal, provincial and territorial

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governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the pan-Canadian VISP.

Questions and Answers

Q1. What is the purpose of a Vaccine Injury Support Program (VISP)?

The VISP will provide financial support to people in Canada in the rare event that they experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada, on or after December 8, 2020. The program will also provide death benefits and support for funeral expenses in the rare case of a death as a result of having received a Health Canada authorized vaccine.

Building on the model in place in Québec for more than 30 years, the VISP will strengthen national immunization campaigns by ensuring fair and equitable access to support for all individuals in Canada who experience a serious and permanent injury as result of receiving a Health Canada authorized vaccine. This program will bring Canada in line with a growing number of countries who have similar no-fault programs in place.

Q2. Who is eligible for the Vaccine Injury Support Program?

In order to be eligible for the VISP, an individual must have experienced a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada on or after December 8, 2020.

Claimants will have up to three years after the date of vaccination, or date of death, in case of a claim for a death benefit, to file a claim. When a serious and permanent injury becomes apparent gradually, the time limit will run only from the day the injury first becomes apparent.

Québec will continue to administer its existing provincial program, which has been in place for over 30 years. Individuals vaccinated in all other provinces and territories will receive coverage under the pan-Canadian Program.

Health Canada authorized vaccines administered to members of the Canadian Armed Forces, Government of Canada officials, and their dependents who are deployed or posted outside of Canada are considered to have been administered in Canada for the purposes of the VISP.

Canadians who experience a vaccine-related injury in another country are not eligible for coverage through VISP. However, some other countries also have vaccine compensation programs, and compensation may be available depending on where the vaccine was administered.

For more information about the pan-Canadian Program, please visit: https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html or visit vaccineinjurysupport.ca.

Q3. Why is the eligibility date retroactive to December 8, 2020?

The December 8, 2020, eligibility date was set to ensure that the program was accessible to all individuals in Canada who have received a COVID-19 since the launch of the national vaccination campaign in December 2020.

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Q4. What constitutes a serious and permanent injury?

A serious and permanent injury is defined as a severe, life-threatening or life-altering injury that may require in-person hospitalization, or a prolongation of existing hospitalization, and results in persistent or significant disability or incapacity, or where the outcome is a congenital malformation or death.

Q5. What measures are in place to protect a claimants' personal information?

The Public Health Agency of Canada is not involved in the collection or handling of personal information under the VISP. RCGT Consulting, as the third party administrator of the VISP, will be handling all claimants' personal information. Under the terms of its contribution agreement, RCGT Consulting is required to ensure systems and procedures are in place to protect personal information. RCGT Consulting must also respect all applicable federal/provincial and/or territorial privacy legislative requirements with regards to the safeguarding of personal information of VISP claimants, beneficiaries and others.

Q6. What kind of financial support will the VISP provide?

Eligible individuals may receive income replacement indemnities; injury indemnities; death benefits; coverage for funeral expenses; and reimbursement of eligible costs such as otherwise uncovered medical expenses.

Q7. How much compensation can an individual receive under the program?

The amount of compensation an individual will receive will be determined on a case by case basis. RCGT Consulting is responsible for providing compensation that is comparable to what is provided through the Government Quebec's compensation program, and informed by other public and private sector injury compensation practices.

Q8. How will you determine causality between vaccine and injury, process a claim, and issue financial support payments?

Timelines for a determination of eligibility and support will depend on the nature and complexity of the claim. All claims will be individually assessed by RCGT Consulting and their team of medical experts. The process will include a review of all required and relevant medical documentation, as well as current medical evidence, to determine if there is a probable link between the injury and the vaccine. If there is a probable link, the medical experts will also assess the severity and duration of the injury. This information will be used by RCGT Consulting to determine the types and levels of financial support awarded to the individual or their survivor(s).

Q10. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency, such as a pandemic, a large portion of the population is vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals while still undergoing thorough safety processes and requirements, to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

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Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs to ensure they can be sold.

Q11. Does the Government of Canada continue to monitor a vaccine's safety after it is authorized?

Canada has a robust and well-established post-market vaccine safety surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Vaccine manufacturers are required to continue to collect information about the long-term safety and effectiveness of their products. Pfizer BioNTech and Moderna, for example, will be following clinical trial participants for at least two years after receiving the second dose of the vaccine. Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

Q12. What is the Government of Canada doing to ensure Canadians have confidence in the safety of the vaccines available to them?

Health Canada only authorizes a vaccine or drug if evidence demonstrates that its benefits outweigh the risks and it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing all COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that the department will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available.

COVID-19 vaccine(s) are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing

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monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q13. How are safety signals identified and when is action taken?

Commented [KM1]: Approved April 23

Safety signals include any information indicating a new association between a vaccine and an event that could affect health, such as a health event that is either unknown or incompletely documented to date. It could also indicate a new aspect of a known association. These concerns include a possible increase in the severity or frequency of expected AEFIs, or one or more unexpected events (i.e., an event that is not consistent with Canadian product information or labelling).

Detecting safety concerns is the primary purpose of post-market vaccine safety monitoring (i.e., once a vaccine is made available to the Canadian public). Health Canada and the Public Health Agency of Canada have a robust vaccine safety surveillance system in place that engages healthcare professionals, vaccine manufacturers, the provincial and territorial health authorities, and Indigenous partners.

The Canada Vigilance Program, managed by Health Canada, receives AEFI reports from Canadian hospitals, healthcare professionals and consumers, as well as from manufacturers and distributors who are required to report all domestic and serious international AEFIs. Similarly, the Canadian Adverse Events Following Immunization Surveillance System, managed by PHAC, receives AEFI reports from all provincial and territorial public health authorities and federal departments. AEFI reports are monitored continuously by the Public Health Agency of Canada and Health Canada using standardized analytic techniques. Any new or unusual adverse events, or changes in trends or severity of specific events would trigger an investigation, including an in depth medical review and risk assessment.

Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

The signal of thrombosis with thrombocytopenia was identified based on foreign reports of these very rare events. Health Canada has already taken action by updating the product monograph and issued risk communications to ensure that health professionals and vaccine recipients have the information they need to identify and manage these events should they occur. The Department will continue to work with international regulators and review data and evidence as it becomes available, including as it pertains to these rare events.

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Public Health Agency of Canada | Agence de la santé publique du Canada

News Release
For Immediate Release

Government of Canada announces launch of the Pan-Canadian Vaccine Injury Support Program

June 1, 2021 (TBC) Ottawa, ON Public Health Agency of Canada

Vaccination is one of the most effective ways to protect Canadians, their families and communities from getting and spreading a serious illness. The Government of Canada is committed to ensuring that everyone who support public health by being vaccinated in Canada are also supported, should they experience a serious and permanent injury as a result of the vaccination.

Today, the Honourable Patty Hajdu, Minister of Health, announced the launch of the Vaccine Injury Support Program (VISP). The program, administered by RCGT Consulting, provides access to financial support for people who have been vaccinated in Canada with a Health Canada authorized vaccine, in the rare event that they experience a serious and permanent injury from that vaccination.

Commented [KM1]: Hyperlink to Canada.ca VISP web content

Commented [AI2]: Used acronym for RCGT Consulting rather than spelling out the name at the request of the organization - it's what they want to be referred to as.

Canada has a rigorous system in place to ensure that all vaccines are safe and effective in preventing the diseases they target before they are authorized for use. Like any medication, vaccines can cause side effects and reactions. After being vaccinated, it is common to have mild and harmless side effects; this is the body's natural response to building immunity against a disease. However, it is also possible, although rare, to have a serious adverse reaction to a vaccine.

The implementation of the VISP strengthens Canada's immunization system and brings Canada in line with a growing number of countries that have such programs in place, including all G7 counterparts. Building on the model in place in Québec for more than 30 years, the VISP will ensure individuals in Canada who experience a serious and permanent injury as result of receiving a Health Canada authorized vaccine have fair and equitable access to support that may include:

- income replacement
- injury indemnities
- death benefits including funeral expenses
- other eligible costs, such as uncovered medical expenses

Vaccines continue to be closely monitored once on the market. Health Canada and the Public Health Agency of Canada continue to review all the available safety data from clinical studies and post-market surveillance, and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians.

Quotes

"Vaccines are an essential tool against many serious diseases, including COVID-19. By choosing to get vaccinated, you chose to protect yourself, your family and your community. This program is in place for you, so that you have access to support should you need it."

The Honourable Patty Hajdu
Minister of Health

Quick Facts

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- The Government of Québec continues to administer its existing Vaccine Injury Compensation Program. Individuals vaccinated in Quebec can apply for support through the Government of Québec's program.
- Over 20 countries around the world have national vaccine injury support programs, including all other G7 countries.
- The VISP will provide financial support to people in Canada in the rare event that they experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, only if administered in Canada, on or after December 8, 2020.
- For information on eligibility, the claims assessment process, and how to apply, call 1-833-489-0839 or visit vaccineinjurysupport.ca.

Commented [KM3]: Hyperlink to RCGT Consulting

Associated Links

Canada.ca/covid-vaccine
Vaccineinjurysupport.ca

Commented [KM4]: Hyperlink to RCGT Consulting

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SM Tracking Number *(to be filled by Social Media Advisor)*: 0521-0075

Social Media Plan – for the launch of the Vaccine Injury Support Program

Context: On June 1 (TBC), the Public Health Agency of Canada (PHAC) will announce the launch of the Vaccine Injury Support Program, the third party administrator (RCGT Consulting) and their readiness to accept claims from people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada.

The VISP web content on Canada.ca will be updated to include information on:

- Launch of the program;
- Name of third party administering the program (RCGT) and link to their VISP website, where additional details on the program and how to submit a claim will be available; and
- Program parameters, including the types of benefits that will be available through the program and the eligibility date for applications (December 8, 2020).

The messaging within this plan aims to raise awareness about the implementation of the Vaccine Injury Support Program and the available support to people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine.

Objective :

- Raise awareness about the implementation of the Vaccine Injury Support Program and the available support to people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine.

Audience:

- Media
- Key health stakeholders, including health professional associations and others involved in COVID-19 vaccine deployment and program implementation, including provincial and territorial governments
- The Canadian population, healthcare professionals, public health authorities, territorial and provincial health authorities

Do you have other MO-approval communication products related to this Social Media plan? ☐ No ☒ Yes; please specify which products (i.e., NR, MA, etc.): NEP, NR, MLQ&A, Web _____
Lead Program Branch: PHAC: IDPC

Program Directorate: IDPC - CENTRE FOR IMMUNIZATION AND RESPIRATORY INFECTIOUS DISEASES

Important Template notes:

- *When submitting a new social media plan, always ensure you are using the latest template, by referring to the version on our GCconnex page: https://gcconnex.gc.ca/file/group/30524010/all#33291829*
- *When drafting tweets and LinkedIn posts, keep in mind that the translation is often longer. English tweets should not exceed 225 characters and English LinkedIn posts should not exceed 600 characters for this reason. The character limit on Twitter is 280 (including spaces) and the character limit on LinkedIn is 700 (including spaces).*
- *All posts should include a web link. The link will take up 23 characters when shortened with the ow.ly link shortener. Ow.ly shortened links allow us to track the performance of the posts. As a result, vanity URLs are not the best option for social media posts and will not be used (as advised by the Web Team, Principle Publisher and Treasury Board Secretariat).*

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SM Tracking Number *(to be filled by Social Media Advisor)*: 0521-0075

- *Include appropriate hashtags, tags and a link to web content in your post.*
- *Send completed template to : hc.cpab.social.media-medias.sociaux.dgcap.sc@canada.ca*
  - *If plan includes Ministerial tweets copy: hc.minsantecan-cdnminhealth.sc@canada.ca*
  - *If plan includes CPHO tweets send all new requests and related emails to: hc.gocc-sacm.sc@canada.ca*
    - *For CPHO tweets with hashtags, tags and links to web content, no more than a combination of three of these is recommended per post.*
  - *If a plan includes @GC_NewsRoom tweets, please note that these are taken care of by MinServ, not the Health Canada or CPHO Social Media teams. GC Newsroom tweets can only be added when a news product is released on Canada.ca/News and generally do not include images.*
  - *If plan includes Travel Health posts, please note that they need to be coordinated with the GAC social media team. Please include all travel health posts in the Travel Health section below.*
- *For tips and tricks on writing social media content, including writing for the different audiences of each platform, and to better understand the social media process, please refer to the Social Media Guide documents, also available on our GCconnex page.*

HEALTH THEME SOCIAL MEDIA

- Please add content in the following order, if applicable: @NewsroomGC/@salledepresseGC, @CDNMinHealth/@MinSanteCAN Twitter, @GovCanHealth/@GouvCanSante Twitter, Healthy Canadians/Canadiens en santé Facebook, HC/SC LinkedIn , PHAC/ASPC LinkedIn

Date	Time	English Message	French Message	Images (English and French)	English Image text + Alt Text**	French Image text + Alt Text**	Hootsuite Tags *(to be filled by Social Media Team)*
	Twitter: @NewsroomGC/@salledepresseGC						
June 1 (TBC), 2021		Government of Canada launches pan-Canadian no-fault Vaccine Injury Support Program.					
	Twitter: @GovCanHealth/@GouvCanSante						**Lin**
		RT CPHO's TW					
	LinkedIn: HC/SC and PHAC/ASPC						**LinkedIn: HC/SC and PHAC/ASPC**

Commented [KM1]: Link to NR

Commented [JD2]: @GCNewsroom TW are handled by Comms Coord

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SM Tracking Number *(to be filled by Social Media Advisor)*: 0521-0075

Date	Time	English Message	French Message	Images (English and French)	English Image text + Alt Text**	French Image text + Alt Text**	Hootsuite Tags *(to be filled by Social Media Team)*
June 1 (TBC), 2021		Today, the Public Health Agency of Canada launched a pan-Canadian no-fault Vaccine Injury Support Program (VISP). The VISP will provide financial support to people in Canada in the rare event that they experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada. For more information about the pan-Canadian Program visit: https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html or visit vaccineinjurysupport.ca.					

Commented [JD4]: Suggest this image

Commented [KM3]: Hyperlink to RCGT webpage when available

CPHO SOCIAL MEDIA

- All CPHO SM content/emails should be submitted directly to the team inbox at **hc.aocc-sacm.sc@canada.ca. Please include the latest approval chain with your plan at the bottom.**
- Note on CPHO Date/Timing: Advisors can be as specific or open-ended/flexible with timing as they wish. For example, you could specify a day, "Month of…", "Week of…", "Flexible", "TBC" etc. The AOCC SM team will post according to their schedule flow unless a specific timestamp is required for events, etc.

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SM Tracking Number *(to be filled by Social Media Advisor)*: 0521-0075

Date	Post Timing (if specific)	English Message	French Message	Suggested Images	English Image Caption/Text	French Image Caption/Text
	Twitter: @CPHO_Canada/@ACSP_Canada					
Banner: *(*Suggested dates)*	*(*D/M/Wk or other time span)*	Banner description: *(New! CPHO account banner: You can recommend the CPHO adopts a banner for her Twitter account based on a topic/theme.)*		*(*Usually follows the look of your other images/suggest an image. See the CPHO's account for an example.)*	Banner caption:	Banner caption (Fr):
June 1, 2021 (TBC)		Today the Public Health Agency of Canada launched a Vaccine Injury Support Program that will support people in Canada who have experienced a serious and permanent injury after receiving a Health Canada authorized vaccine. For more information, visit: https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html				

Approved by:

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Support Program

Canada has very high standards for vaccine safety. Health Canada:

- only authorizes vaccines in Canada after a thorough and independent review of the scientific evidence
- works with others to monitor vaccines on the market, and can quickly make changes if they identify safety concerns

Only vaccines that are proven to be safe, effective and of high quality are approved for use in Canada. As with all vaccines and any medication, there's a chance that there will be a serious side effect. These are rare, but they do happen.

On December 10, 2020, the Government of Canada announced that it was creating the **Vaccine Injury Support Program.**

The Program will provide financial support to you if it is determined that you have experienced a serious and permanent injury after receiving a Health Canada-authorized vaccine, administered in Canada on or after December 8, 2020. Financial support is also available to you if you are the dependent or succession of an individual who has died after vaccination.

Supports provided may include:

- income replacement
- payment for injuries
- death benefits including funeral expenses
- other eligible costs, such as uncovered medical expenses

After a competitive process and a thorough review, RCGT Consulting was selected to administer the program, which is now accepting claims.

For more information on eligibility, the claims assessment process and how to apply please, visit RCGT Consulting's website at vaccineinjurysupport.ca.

Commented [SP1]: French site: soutienvictimesvaccination.ca

For individuals vaccinated in Quebec: The Government of Québec will continue to administer its existing Vaccine Injury Compensation Program. Individuals

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

vaccinated in Quebec are required to apply for support through the Government of Québec's program.

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From: Tam, Dr Theresa (PHAC/ASPC)
Sent: 2021-05-18 10:46 AM
To: Thompson, Kathy (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Diogo, Brigitte (PHAC/ASPC)
Subject: Fwd: CBC.ca: Canadians 'may' be able to travel to U.S. for vaccines without quarantine on return

---

What is the status in terms of provinces wanting to get their populations vaccinated in the US?

Did we hear back from MB on their operational plan?

Did we get clarity on vaccine injury compensation responsibilities between US and Canada?

TT

Sent from my iPhone

Begin forwarded message:

> **From:** "Media Monitoring / Suivi des Medias (HC/SC)"
> **Date:** May 18, 2021 at 10:23:37 AM EDT
> **Subject: CBC.ca: Canadians 'may' be able to travel to U.S. for vaccines without quarantine on return**
>
> Dist: HC.F PEIA COVID19 / COVID19 AREP F.SC >; HC.F PEIA Ministers Monitoring / Surveillance des medias ministre AREP F.SC
> May 18, 2021
> **Canadians 'may' be able to travel to U.S. for vaccines without quarantine on return**
> *Windsor Regional Hospital's CEO wrote to officials seeking clarity on the issue*
> Source: cbc.ca/windsor
> If Canadians were to get vaccinated against COVID-19 in Detroit, they might be able to do so without having to quarantine upon reentry to Canada.
> That's according to a letter sent from the Public Health Agency of Canada (PHAC) to Windsor Regional Hospital CEO David Musyj.
> Musyj, who is one of a number of local officials pushing for Canadians to gain access to U.S. vaccines, wrote to the federal agency requesting a ruling on whether getting a vaccine would be considered receiving an "essential medical service or treatment" under the current emergency measures at the border.
> Receiving such services is one of the reasons a traveller could be exempt from the two week-quarantine and COVID-19 testing requirements laid ut by the federal government.
> In a follow up note to PHAC, Musyj indicated that a large health-care institution in Detroit is interested in providing vaccines to Canadians.
> PHAC told Musyj that receiving a COVID-19 vaccine would be considered essential, and if Canadian travellers meet certain requirements, they "may" be exempt from the re-entry requirements.
> The exception would be in place for a traveller as well as a support person, and they must arrive in a private vehicle with a letter from a health-care professional indicating that the treatments are essential, as well as written evidence from a professional on the other side of the border stating that the treatment had occurred.
> The letter said that the onus is on the traveller to provide the proper documentation, and suggested that no other stops could be made on the trip.

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As Musyj pointed out in a note to staff at the hospital, any Canadians entering the U.S. would also be subject to U.S. entry requirements.
https://www.cbc.ca/news/canada/windsor/covid19-vaccines-windsor-regional-hospital-1.6030647

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From: Tam, Dr Theresa (PHAC/ASPC)
Sent: 2020-06-14 8:57 PM
To: Charos, Gina (PHAC/ASPC); MacKenzie, Sara (HC/SC); Allison, Catherine (HC/SC); Elmslie, Kim (PHAC/ASPC); Namiesniowski, Tina (PHAC/ASPC)
Cc: Njoo, Howard (PHAC/ASPC)
Subject: Fwd: COVID-19: Social Media and Stakeholder Trends – June 14

We may get asked about a vaccine injury compensation program.

May also be asked whether the federal giv will provided indemnification for any COVID pandemic vaccine.

TT

Sent from my iPhone

Begin forwarded message:

> **From:** "Media Monitoring / Suivi des Medias (HC/SC)"
> **Date:** June 14, 2020 at 16:00:52 EDT
> **Subject: COVID-19: Social Media and Stakeholder Trends – June 14**
>
> Distribution group/Groupe de distribution: HC.F PEIA COVID19 / COVID19 AREP F.SC; HC.F PEIA Ministers Monitoring / Surveillance des medias ministre AREP F.SC;
>
> **Trending Headlines**
>
> - **High spread:** Officials close Beijing market, lock down area after new COVID-19 outbreak (Global) – **11.1k shares**
> - **High spread:** Active Edmonton COVID-19 cases rising while Calgary cases drop (CTV) – **6.6k shares**
> - **High spread:** COVID-19 vaccine: experts call for injury compensation program (CTV) – **3.9k shares**
> - **High spread:** Inquiétante hausse du nombre de cas de COVID-19 en Chine (TVA) – **3k shares**
> - **High spread:** La « sobriété touristique » pourrait avoir meilleur goût dans l'après-COVID-19 (Radio-Canada) – **2.6k shares**
> - **High spread:** COVID-19 returns to Northwood, resident tests positive (CBC) – **2.2k shares**
> - **High spread:** N.S. reports no new cases of COVID-19 for fifth straight day; day cares to open Monday (CTV) – **2.1k shares**
> - **High spread:** COVID-19 disability benefit, even if approved, would 'miss all kinds of people' (Global) – **2.1k shares**
> - **High spread:** Two new cases of COVID-19 in Manitoba on Saturday (CTV) – **1.9k shares**
> - **High spread:** Des travailleurs d'épicerie déçus par la fin des primes de 2 $ de l'heure (Radio-Canada) – **1.6k shares**
> - **High spread:** Some Canadians say coronavirus was the push they needed to the leave the city for good (Global) – **1.6k shares**
> - **High spread:** New Brunswick reports second COVID-19 death, three new cases in Campbellton region (CTV) – **1.5k shares**
> - **High spread:** Canada's coronavirus death toll up by 27 as COVID-19 cases surpass 98,000 (Global) – **1.5k shares**
> - **High spread:** Ontario records 197 new cases of COVID-19 and 12 more deaths (CTV) – **1.4k shares**
> - **High spread:** Blood Tribe elder has become the first member of an Alberta First Nation to die of COVID-19 (CJWE) – **1.4k shares**
> - **High spread:** Why those under 40 now make up the majority of COVID-19 cases in Alberta (CBC) – **1.1k shares**
> - How 'superspreading' helps drive the coronavirus pandemic (Global) – **687 shares**
> - AstraZeneca agrees to make COVID-19 vaccine for Europe (AP) – **596 shares**

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- Greece's strict lockdown kept coronavirus deaths under 200. Now it wants to reopen (Global) – **552 shares**
- New COVID-19 cases in Quebec stay below 200 for sixth day, hospitalizations drop again (iheartradio) – **493 shares**

Stakeholder News Releases

- **CDC: Consolidated COVID-19 testing recommendations**
- **WHO: A cluster of COVID-19 in Beijing, People's Republic of China**

Stakeholder Tweets

U.S. Centres for Disease Control (@CDCgov)

- While shopping for groceries and other household items, order online or over the phone if possible. Pick up curbside or ask for deliveries to be left on your doorstep to avoid person-to-person contact. Get more tips: https://t.co/qOJIH3XUI5 https://t.co/tuM0yFvGaW

World Health Organization (@WHO)

- The #COVID19 pandemic has caused even greater shortages in the blood supply. To help patients and healthworkers: Keep blood drives going, Ensure safety measures are in place, Encourage people to keep donating blood, #GiveBlood, save lives, give safely #WorldBloodDonorDay https://t.co/nDnkZjXrdK
- RT @WHOSom: Today is #WorldBloodDonorDay. In this #COVID19 situation, more than ever, saving lives through voluntary blood donation is important. Give blood and make the world a healthier place. https://t.co/f3wiMyXn7p
- RT @DrTedros: We are still letting pandemic politics divide us and make us less safe. We can be better than that! I will say it once again: Quarantine #COVID19 politics!
- RT @DrTedros: Our message on #WorldBloodDonorDay is: keep donating blood and saving lives. Giving blood during #COVID19 is safe, provided physical distancing and hygiene measures are respected.
- FACT: The prolonged use of medical masks when properly worn, DOES NOT cause CO2 intoxication nor oxygen deficiency More: https://t.co/TdKoGmWrIr #coronavirus #KnowTheFacts https://t.co/tRtfB4pf2V
- Every day, even during a pandemic like #COVID19, regular blood donations are needed all over the world to ensure individuals & communities have access to safe & quality-assured blood & blood products. Safe blood saves lives: https://t.co/PFSmRJXwa3 #WorldBloodDonorDay https://t.co/j7yGgQFmWK

Summaries

Canadian Coverage

Canada's coronavirus death toll up by 27 as COVID-19 cases surpass 98,000

Global News (Maryam Shah)

As reported by Global News, for the second time in a month, the daily coronavirus death toll in Canada fell below 30. Technically, the official COVID-19 numbers released on Saturday, June 13, show a daily death toll of 58. But Quebec reported 31 deaths that were prior to June 5, leaving the actual death toll from the past 24 hours much lower, at **27**. COVID-19 cases across the country **increased by 465**, with the bulk of them originating in Ontario (266) and Quebec (158). Overall, Canada has seen **8,107 deaths** from COVID-19 and **98,392 cases**. More than **59,000** people are considered **recovered**. The country has conducted **2.2 million tests** so far.

COVID-19 disability benefit, even if approved, would 'miss all kinds of people'

Global News, Erica Alini

As reported by Global News, on June 5, the federal government promised a **one-time payment** of up to **$600** for Canadians living with **disabilities** to help lessen the financial strain tied to the novel coronavirus pandemic. That financial aid is now in limbo, as the measure was part of a bill that failed to receive bipartisan support on Wednesday, June 10. But even if Ottawa finds a way to deliver the income support, as government officials have vowed to do, the funds will remain out of reach for a significant share of Canadians with disabilities. The money "misses all kinds of people," said Ottawa resident Robert Morley. Only those with a valid certificate for the DTC, a non-refundable credit for people with disabilities and their families, would be eligible to receive Ottawa's COVID-19 aid. And while that would ensure the income support would reach some 1.2 million people, it also means it **wouldn't reach hundreds of thousands** more Canadians with disabilities, many of them in low-income households, who don't have the DTC, according to experts.

As the race for a vaccine ramps up, so do calls for vaccine injury compensation

CTV News

According to CTV News, Canada may be at the forefront of the race to develop an effective COVID-19 vaccine, with a clinical trial already approved, but experts warn we have fallen short in developing a **fund to compensate those who may be injured** by vaccinations. With immense political and public pressure to develop a vaccine, a process that can take years, researchers are carrying out **trials at an unprecedented pace** in efforts to bring a successful vaccine to market in a matter of months. And

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although vaccine-related reactions are rare, experts say a new vaccine -- especially one developed using new technology -- may come with **unknown risks**. At least 19 countries already have programs in place that compensate individuals injured by vaccines, but Canada does not. In fact, it is the **only G7 country without such measures** in place, and experts are now calling on the federal government to prepare in advance of the COVID-19 vaccination program.

Provincial and Territorial Coverage

Why those under 40 now make up the majority of COVID-19 cases in Alberta

CBC News (Pamela Fieber)

CBC News reported that younger people have become the majority of Alberta's active COVID-19 cases. Alberta's chief medical officer of health **Dr. Deena Hinshaw** said that in the weeks since reopening, there have been an increase of infections among younger Albertans. "Over the past few weeks province-wide, we have begun to see a younger demographic testing positive for COVID-19," Hinshaw said. "**Sixty per cent** of our currently active cases are under the age of 40. And we are seeing a particular increase in those between 20 and 29." Vanessa Meier-Stephenson, an expert in infectious disease at the University of Calgary, said the uptick is not completely unexpected but remains concerning. "It certainly could be related to **groups getting together**, a little bit of **social distancing fatigue**," she said. "The younger population is much more social. Meier-Stephenson said the upsurge in cases in the U.S. suggests that any time the restrictions are eased, the number of cases will rise.

Blood Tribe elder has become the first member of an Alberta First Nation to die of COVID-19

CJWE FM

According to CJWE FM, the Blood Tribe has announced that an elder died earlier this week from complications due to COVID- 19. According to a press release, the Blood Tribe Emergency Management Team is continuing its containment efforts to keep the COVID-19 virus from spreading within the Blood Reserve and that the announcement respected the time and space of family and friends in coping with their significant loss. The Blood Tribe wants members to avoid gathering in large groups with members outside of their household, but if need be, please respect the 15-person maximum indoor rule and the 50-person outdoor rule. "Anyone not abiding by these rules can be subject to fines."

New Brunswick reports second COVID-19 death, three new cases in Campbellton region

CTV News (Allan April)

As reported by CTV News, a second New Brunswick resident has died from COVID-19, the province announced on June 13. Public Health says the individual died in the **Campbellton region** of Zone 5. They were one of the cases **connected to the ongoing outbreak** in Zone 5 and had been a resident of the Manoir de la Vallée in Atholville prior to being admitted to the hospital.

International Coverage

Greece's strict lockdown kept coronavirus deaths under 200. Now it wants to reopen

Associated Press

As reported by the Associated Press, heavily reliant on tourism, Greece is officially **reopening to foreigners** on Monday, June 14, after closing its borders to most during the coronavirus pandemic. Its hopes are pinned on popular tourist destinations such as Mykonos and the islands of Rhodes, Corfu, Crete and Santorini, where regular ferry service already resumed and direct international flights are set to restart on July 1. The Greek government has taken a gamble in deciding to relax COVID-19 health inspections at ports and airports in order to **avoid another crippling recession**, having only recently emerged from an economically painful period sparked by the international financial crisis.

AstraZeneca agrees to make COVID-19 vaccine for Europe

Associated Press

According to the Assocaited Press, drugmaker **AstraZeneca** struck a deal Saturday, June 13, to supply up to **400 million doses** of an experimental COVID-19 vaccine to European Union countries, the latest in a series of agreements as scientists, governments and pharmaceutical companies race to combat the virus. AstraZeneca plans to begin delivering the vaccine to European countries by the **end of this year** under the agreement with the Inclusive Vaccine Alliance, formed this month by France, Germany, Italy and the Netherlands. All other EU member states will have the chance to take part under the same terms as the original alliance members. The cost of making the vaccine, which was developed by Oxford University, is expected to be offset by funding from the governments.

Officials close Beijing market, lock down area after new COVID-19 outbreak

Associated Press

According to the Associated Press, the largest **wholesale food market** in Beijing was shuttered behind police guard and the surrounding neighbourhood locked down Saturday, June 13, after more than **50 people tested positive** for the coronavirus in the Chinese capital. The outbreak — coming more than 50 days after the last local case in the city of 20 million people — showed how the virus can still come back as restrictions are eased. The city's swift response reflected China's emphasis on moving quickly to stem the spread of new cases wherever they appear, a lesson learned from fighting the outbreak earlier. "The **epidemic was already almost over**, and then suddenly there's one or two more new hot

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spots," said Jin Zheng, a woman in her 20s walking in central Beijing. "I'm a little scared. I hope everyone avoids going outside too much and wears protective gear."

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Pan-Canadian Public Health Network
Partners in Public Health

Réseau pancanadien de santé publique
Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
April 1, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T
NL:
PE:
NS:
NB:
QC:
ON:
MB:
SK:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Mark Sagan
HC/BRDD: Robert Pless
VSWG: Alan Thom
VVWG: Amanada Shaw,
CIRC: Nicolas Gilbert,
DND: Marie-Christine Lamontagne
CSC: Bassem Guirguis
PHAC: Bryna Warshawsky

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed members and reminded the committee to submit responses to the short mid-year check-in survey and to submit responses to the questions regarding COVID-19 immunization records to the CIC Secretariat by end of day April 6, 2021. Erin (CIC Federal Co-Chair) also informed members that the CIC Secretariat did not receive any nominations for the PT co-chair position, therefore it will be considering moving to a monthly rotating chair model.

2. COVID-19 Vaccination Coverage Update

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ATIA - 13(1)(c) ATIA-14(a)

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Nicolas Gilbert (CIRC Federal Co-Chair) provided a COVID-19 vaccination coverage update based on reports that were submitted by PTs on March 29, 2021. Nicolas (CIRC Federal Co-Chair) informed members PHAC hopes to start reporting on adults in aged 60-69 years and in younger adults in two weeks. The data collection form will be modified to allow for a more detailed coverage breakdown below the age of 65. Nicolas (CIRC Federal Co-Chair) noted that it will be very important that the AstraZeneca and COVISHIELD products are distinguished in PT registries not only for coverage purposes, but also because the coverage tables are the denominators for the AEFIs rates.

BC asked which date PHAC is expecting to make the change to the template. Nicolas (CIRC Federal Co-Chair) replied that the updated data collection form will be sent to PTs on April 10, 2021 and PTs can start using that form on April 13, 2021. CIRC will send the new categories that will be included on the updated form to PTs on April 6, 2021, for their information.

3. COVID-19 Vaccine Safety Update

Amanda Shaw (VVWG Federal Co-Chair) informed members that 329 AEFIs have been reported since the last update, and that the majority continue to be in females. Two deaths were reported since the last update. Of all the deaths that have been reported to date, 14 have been determined to not be causally linked to the vaccine and the other 12 deaths remain under investigation.

Amanda (VVWG Federal Co-Chair) noted that is it critical that PHAC receives the doses administered by vaccine brand as it helps to determine vaccine surveillance rates.

BC asked if the local reactions meet sufficient severity criteria to be reportable. AB commented that in their province, [redacted] Amanda (VVWG Federal Co-Chair) agreed and noted that PHAC is taking in whatever PTs are submitting and that criteria varies by PT so that would be reflected in the data.

BC commented that one of their strategies has been to do more communication to reporters to not report expected side effects. Amanda (VVWG Federal Co-Chair) noted that PHAC is in ongoing discussions regarding whether it should be advising the same, however, there are concerns regarding an increase in non-serious AEFIs being missed if this is done.

4. Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)

Bryna Warshawsky (PHAC) provided an in-depth overview of what is known to date regarding Vaccine-Induced Prothrombotic Immune Thrombocytopenia, including reported rates in other countries and implications for Canada.

Amanda Shaw (PHAC) confirmed that the combination of blood clotting and the low platelet count has not been seen in Canada in either CAEFISS or Canada Vigilance. BC asked what the biologic plausibility is of why this is happening in younger people and females primarily. Bryna (PHAC) replied that it is unknown whether this is a phenomenon of who the vaccine was first given to, as most countries chose to vaccinate HCWs (which tend to be female) given that efficacy data was unavailable in individuals over 65 years of age, or if there is something unique about this group. Bryna (PHAC) added that the UK has been using AstraZeneca in older people but PHAC has not seen solid surveillance data from the UK, and noted that they're working on it and it will be helpful as they're using the vaccine in older age groups.

AB asked if Bryna (PHAC) would be open to providing the same presentation to VVWG. Bryna (PHAC) replied yes.

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BC asked if the presentation deck could be shared with vaccine safety committees within jurisdictions. Erin Henry (CIC Federal Co-Chair) confirmed that it could be shared with vaccine safety groups within PTs.

MB asked, given that Canada is about to immunize a large number of people with the AstraZeneca vaccine very quickly starting next week, why Canada wouldn't consider pausing administration for a week until we have more certainty from the EU and other countries. Bryna (PHAC) acknowledged that this is a good question and noted that risk-benefit is a really challenging area. The EMA came out yesterday saying that they have had 61 cases and they considered the risk to be very small.

BC asked if PHAC or Health Canada have enough information available to develop a case definition for VIPIT. Amanda (PHAC) replied that a case definition is currently being developed and continues to be updated. The case definition will be presented to VVWG and Amanda (PHAC) noted that it could also be presented to CIC/VSWG at the next meeting on April 6, 2021. PHAC has also been getting some input from the Brighton collaboration group on where they're at with their case definition as well.

BC commented that PHAC will need to revisit the data captured through the federal reporting form for events like this and that more nimbleness will be required in surveillance systems. Priorities with respect to data capture around emerging events need to be revisited.

5. Roundtable

Members were asked to comment on the following questions:

Q1 – Is your jurisdiction aware if immunizers have been able to obtain more than 10 doses per vial of COVISHIELD in your province?

Q2 – Is your jurisdiction withholding the vaccine for individuals who have had a confirmed COVID-19 infection for 3 months, as per NACI's recommendations in the context of limited supply?

YK replied as follows:

Q1 – Question not applicable to YK.

Q2 – YK was unable to comment.

NT replied as follows:

Q1 – Question not applicable to NT.

Q2 – In general, NT has been waiting three months to vaccinate individuals who have had a confirmed COVID-19 infection, however, NT has also occasionally administered the vaccine because the individual was travelling, a HCW, or at higher risk.

BC replied as follows:

Q1 – BC has not surveyed immunizers to determine if they have been able to obtain more than 10 doses per vial of COVISHIELD, however, BC commented that they have been hearing more reports about the inability to withdraw six doses from the Pfizer vial from several locations, and that they are trying to get more information about the type of injection equipment that is being used in these locations.

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Q2 – BC is not recommending withholding the vaccine for individuals who have had a confirmed COVID-19 infection for 3 months as a routine practice – immunization is recommended once a person has fully recovered from COVID-19 infection.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

SK replied as follows:

Q1 – SK conducted a survey and determined that they were able to get 16,500 COVISHIELD doses from 15,500 doses that were anticipated, so they have been able to withdraw more than 10 doses per vial.

Q2 – SK is taking a passive approach on this and will vaccinate an individual who shows up to a clinic and has had a COVID-19 infection within the past three months, however, they are not advertising this (with the exception of LTCFs).

MB replied as follows:

Q1 – MB has heard that immunizers can withdraw an 11th dose but are unsure if they are able to do this consistently.

Q2 – MB has been immunizing individuals who have had a confirmed COVID-19 infection but were unable to comment on the timeframe at which these individuals are immunized.

ON replied as follows:

Q1 – ON was unable to comment.

Q2 – ON is offering vaccine to those who have fully recovered from COVID-19 infection but were unable to confirm the timeframe at which these individuals are immunized.

QC replied as follows:

Q1 – QC has heard some anecdotal reports about immunizers being able to withdraw an 11th dose, however, they have not conducted a survey to collect this information and are not planning to.

Q2 – QC does recommend that individuals with a previous COVID-19 infection wait 3 months following infection before getting the vaccine, however, this is a soft recommendation. The only contraindication QC has, as per standard vaccines when an individual has an acute illness, is that the individual must complete the isolation period before receiving their vaccine at a clinic if they have had a confirmed COVID-19 infection. QC also noted that, similar to France, they are following a one-dose schedule for individuals with past COVID-19 infection, though there are some nuances with this depending on when the COVID-19 infection occurred.

NS replied as follows:

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Q1 – NS commented that they raised this question and noted that some groups in their province have been routinely able to withdraw more doses than expected, including up to 12 doses per vial.

Q2 – NS is not withholding vaccine for individuals with a history of confirmed COVID-19 infection.
NB replied as follows:

Q1 – NB has not heard of immunizers being able to withdraw more that 10 doses per vial of COVISHIELD.

Q2 – NB commented that they raised this question and noted that they currently immunize individuals with a previous COVID-19 infection without any limitation on time, but their Medical Officer of Health was expected to make a decision on this today and would likely follow NACI's recommendation of 3 months.

PE replied as follows:

Q1 – PE has not had reports of immunizers being able to withdraw more that 10 doses per vial of COVISHIELD.

Q2 – PE does not delay immunization for individuals with a previous COVID-19 infection.

NS commented that they will require the manufacturing information for the AstraZeneca product coming from South Korea, and asked if there will be separate Product Monographs (PMs) for the AstraZeneca products from South Korea and the U.S. Robert Pless (Health Canada) replied that he would enquire about the status of the review of that manufacturing site and what could be provided to NS. Robert (Health Canada) confirmed that the PMs for the AstraZeneca products from South Korea and the U.S. are the same.

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Pan-Canadian Public Health Network
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Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
April 15, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T
NL:
PE:
NS
NB
QC
[redacted]
ON
MB
SK:
AB:
BC
NU
NT:

Invited Participants:
HC/BRDD: Robert Pless
VSWG: Alan Thom
VVWG: Amanada Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
DND: Marie-Christine Lamontagne
CSC: Jennifer Morse
PHAC: Natalia Abraham

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed members and reminded the committee to submit any comments or concerns regarding the proposed monthly rotating co-chair model to the CIC Secretariat by end of day April 16, 2021. Members were also advised that NACI is meeting later this afternoon to discuss the recommendations for AstraZeneca as the committee was unable to finish their deliberations on April 13, 2021. The committee's recommendations will be presented to SAC on April 18, 2021, and released early the week of April 19, 2021. Erin (CIC Federal Co-Chair) also noted that moving forward, the CIC Secretariat will send out the roundtable questions to members in advance of the meeting when possible to help PTs better prepare for the discussion.

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2. COVID-19 Vaccination Coverage Update

Nicolas Gilbert (CIRC Federal Co-Chair) provided a COVID-19 vaccination coverage update based on reports that were submitted by PTs on April 12, 2021. Nicolas (CIRC Federal Co-Chair) noted that some PTs administered more doses of COVISHIELD vaccine than what they nominally received as some immunizers have been able to withdraw up to 11 or 12 doses from the 10-dose vials.

In the territories, more than 2/3 of the adult population have now received at least one dose of COVID-19 vaccine. Nicolas (CIRC Federal Co-Chair) also informed members that for seniors aged 80 years and older, the coverage percentage is above what was anticipated based on the expected proportion of people who indicated intent to be vaccinated against COVID-19 in the surveys conducted by Statistics Canada and PHAC. In addition, this coverage number continues to increase which is positive news. Nicolas (CIRC Federal Co-Chair) flagged that PHAC's Vaccination Coverage team is currently working with CIRC to address an issue regarding individuals who received two doses of different products as this may cause double-counting in the number of doses administered. In the forthcoming weeks, PHAC will start to report coverage for the 50-59 year old and 60-69 year old age groups.

Nicolas (CIRC Federal Co-Chair) then advised members that data collection for the first cycle of the COVID-19 Vaccination Coverage Survey, which was conducted in the territories, is complete and the pre-release will be available on May 5, 2021 followed by the public release on May 12, 2021. The data will be shared with the territories that were included in the cycle, but Nicolas (CIRC Federal Co-Chair) sought feedback from the committee on whether all PTs were interested in receiving a presentation on this data ahead of the public release on May 12, 2021. No provinces expressed interest.

BC asked when Canada-wide survey results will be available. Nicolas (CIRC Federal Co-Chair) replied that the second cycle will focus on provinces and that the data will be available in early June 2021. There will not be a pan-Canadian survey of PTs due to logistical reasons.

3. COVID-19 Vaccine Safety Update

Amanda Shaw (VVWG Federal Co-Chair) informed members that 138 AEFIs have been reported since the last update, and that the majority continue to be in females, though this rate has dropped slightly compared to previous weeks. Four deaths were reported since the last update. Of all the deaths that have been reported to date, 16 have been determined to not be causally linked to the vaccine and the other 15 deaths remain under investigation.

Amanda (VVWG Federal Co-Chair) noted that the rate of adverse events by vaccine brand name will be included in this week's online report. PHAC received one report of Thrombosis with Thrombocytopenia Syndrome (TTS) that will also be included in this week's report.

NB commented that they are trying to get a handle on the surplus of over-reporting that they're receiving in their province on almost any event that occurs post-vaccine and that they have a meeting on April 16, 2021 with their regions to help discern what does and does not need to be reported. NB asked if there is a lot of over-reporting from other PTs, or anxiety about what PTs should report. Amanda (VVWG Federal Co-Chair) replied that PHAC has received similar questions from a couple of PTs, and noted that the CAEFISS position is that PHAC does recommended that these events still be reported as the COVID-19 vaccines are new and PHAC wants to ensure that no safety signals are missed. However, PHAC understands that not all PTs are going to be able to report and process all events. Amanda (VVWG Federal Co-Chair) added that she believes that two PTs are going to stop processing and reporting some of the adverse site reactions, however, PHAC is still accepting these reports at the national level and is going to try to document which PTs are reporting these reactions and which are unable to do so due to the burden of work.

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4. Vaccine Safety Update: Thrombosis with Thrombocytopenia Syndrome (TTS) Case Finding Definition and CAEFISS Reports

Before Natalia Abraham (PHAC) started her update, BC asked if she could also provide a quick update on what transpired at the ACIP meeting on April 14, 2021 with regards to their review of Janssen. Natalia (PHAC) confirmed that she would provide an update.

Natalia (PHAC) informed members that PHAC presented the draft interim case finding definition for TTS from the Brighton Collaboration to CIC and SAC on April 13, 2021, however, on April 14, 2021, PHAC received notice that the Brighton Collaboration would be coming out with revised definitions that are anticipated to be released on April 16, 2021, and that contain fairly significant revisions. PHAC plans to present this new information to the committee at the next CIC meeting along with more supporting arguments and a proposal if there are more appropriate modifications for the Canadian context.

Natalia (PHAC) noted that there are still only two adverse event cases in Canada that would possibly meet the TTS case definition and that only one of those cases has a positive anti-PF4 status. PHAC is hoping to have more analysis for members next week on some of the more detailed characteristics of those who have thrombosis or thrombocytopenia.

With regards to the ACIP meeting, Natalia (PHAC) informed members that the overall outcome is that ACIP stayed their pause on the Janssen vaccine and did not feel like they had enough information to come to any conclusions. They are extending the pause of the Janssen vaccine while they gather more information and they did not have an official vote.

BC asked if PHAC could provide details on the major changes that the Brighton Collaboration is considering. Natalia (PHAC) replied that PHAC did receive some information from one of the Brighton Collaboration members and noted that she was not sure if it would be included in the release on April 16, 2021, but that it's around the PF4 antibody status and also probable and possible case definitions that differ from what PHAC presented to CIC on April 13, 2021. Bryna Warshawsky (PHAC) added that what ACIP is looking at is very similar to what NACI is looking at which is to compare the risks and benefits, and noted that ACIP will determine the date of their next meeting on April 16, 2021.

Erin Henry (CIC Federal Co-Chair) asked if the number of Janssen doses administered in the U.S. was mentioned at the ACIP meeting. BC replied that the U.S. has administered 7.2M doses.

Erin (CIC Federal Co-Chair) informed members that NACI will be discussing the recommendations for Janssen this afternoon and that the committee had hoped to have their recommendations out by next Friday, April 23, 2021, however, they were also going to take into consideration ACIP's recommendations which were expected on April 14, 2021 but have since been postponed, therefore NACI's recommendations could be delayed.

5. Projet-pilote du Québec: évaluation virtuelle / Quebec Pilot project : virtual evaluation

[redacted] (Quebec) provided an overview of Quebec's virtual evaluation pilot project in COVID-19 immunization clinics, which involves a pool of health care workers currently working from home (pregnant or immunocompromised nurses) who have been recruited to conduct pre-vaccination assessments virtually. While the current pilot project involves individuals that receive this virtual assessment at a computer at the clinic site, QC noted that there is a second part to this project that's currently under a feasibility assessment and they are trying to determine if the evaluation can be done remotely prior to the person coming to the vaccination centre (in which case the evaluation would be

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done a couple of days before the vaccination appointment, and the individual would only be asked if anything has changed since the evaluation when they arrive at the clinic). QC added that the evaluation takes approximately three minutes to conduct, and that this model could halve the number of staff required at the immunization clinics.

6. COVID-19 Vaccine Inadvertent Administration Errors

[redacted] (PHO) led a discussion on COVID-19 vaccine inadvertent administration errors, noting that ON is currently working on developing a document that would formalize guidance for these errors. [redacted] (PHO) noted that some of the challenges in developing this document include that there is very limited evidence on the impact of certain errors and what various response options might be. [redacted] (PHO) sought feedback from the committee on what other PTs are doing in this area, and what some different models might look like for the development of guidance in this area recognizing that it's largely expert opinion.

BC commented that they've had issues around exact cold chain or transport, pre-drawing syringes for beyond the six hours that's recommended, administration of expired vaccine, and mixed schedules (e.g. individuals presenting at immunization clinics and not disclosing receipt of a previous dose). BC asked the committee for their thoughts on a coordinated process so that PTs are answering similar questions related to errors in a similar manner, and if there are certain errors that would be of benefit to have central guidance on.

SK commented that their standing Committee on Immunization discussed this on April 13, 2021 and would really like to have national guidance. Oftentimes, SK's MOHs refer to the CDC guidelines, and therefore SK thinks that there's a lot of interest from their province to be part of the development of this guidance and to have something central that the province can reference. SK noted that they have individuals showing up to clinics and not disclosing their previous dose, and that they are also having issues around reconstitution, cold chain, and temperature excursions.

MB commented that they are uncertain if they already have any guidance like this but noted that they would support this document and added that it would be great if it could be collaborated together.

Erin Henry (CIC Federal Co-Chair) advised members that PHAC and CIC could take this on and asked if members could submit any guidance that their jurisdiction has already developed to the CIC Secretariat, and added that Bryna Warshawsky (PHAC) is happy to support this work.

QC commented that they are looking to develop guidance like this based on CDC's documents and would be happy to send their guidance to the CIC Secretariat. QC noted that it will be very helpful for their province to refer to a federal document, but that they have some specificities which requires them to produce their own document. Regardless, they are interested in whatever is produced at the federal level.

NS commented that they would appreciate a national approach to this, and noted that they have a provincial immunization coordinator who most often answers these types of questions, however, the coordinator does have to reach out to the ministry-level for more complicated questions and also at times to the vaccine manufacturers for support for very specific questions.

7. Roundtable

Members were asked to comment on the following questions:

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Q1 – Are PTs aware of declines in infant/toddler and school entry/school child vaccination over the course of the pandemic response period?

- What catch-up planning are they considering to deal with this, and when?

Q2 – In your jurisdiction, are frontline health care workers receiving the second dose of vaccine sooner than the 4 month interval recommended by NACI?

NL replied as follows:

Q1 – NL is not seeing a huge decline in their childhood vaccination rates – initially the province did have some concerns due to no shows, however, those individuals rescheduled their appointments. Their rates continue to be quite high and they still try to offer vaccination clinic appointments to families.

Q2 – NL is currently looking at this however they will not be steering away from NACI's recommendations. Once NL feels that their population has been vaccinated with at least one dose, the timeframe for when they can start providing the second dose may be shortened, but likely still in the 3-4 month timeframe.

NB replied as follows:

Q1 – NB has not yet received or analyzed data from schools with regards to childhood immunization rates, however they have noticed a slight drop in childhood immunization with other clinics but noted that it is nothing to be concerned about. They will be hiring another nurse on their team to look into this and to monitor it closely.

Q2 – NB is staying with NACI's recommendation for the 4 month interval – if the province receives more vaccine and everyone has been offered the first dose, they'll start providing second doses.

NS replied as follows:

Q1 – NS had to pause the second round of their school immunization program (as they did last spring) and they hope to resume the program when it's operationally feasible to do so. NS has been hearing anecdotally that demand for childhood product continues from providers and they are hoping this will be reflected in their coverage rate.

Q2 – HCWs in NS are receiving their second dose at the 4 month interval unless they booked their second dose appointment before the change in recommendations (in which case they would receive their second dose at the 21-28 day interval).

PE replied as follows:

Q1 – PE is seeing minimal to no decline in their childhood immunization rates.

Q2 – Most frontline workers in acute and long-term care were offered their second dose at 21-28 days but anyone receiving their vaccine now are waiting the 4 month timeframe.

QC replied as follows:

Q1 – QC has seen some decline in childhood vaccination coverage but nothing to be concerned about. The reduction in vaccine coverage has been mainly concentrated in urban settings that were most affected by COVID-19 cases. QC plans to catch-up students in the fall of 2021 and are reinforcing that

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immunization is an essential service and should not be delayed. Catch-up will also be done before school entry.

Q2 – All HCWs in QC are vaccinated according to the 4 month interval. QC can use the minimum interval (21-28 days) if there are workers in LTC settings that have received their first dose to complete their vaccination.

ON replied as follows:

Q1 – Anecdotally and using a comparison of previous years' distribution data, demand has decreased in ON [redacted] They are also aware that some local public health units have suspended their school clinics which ON noted [redacted] ON is currently doing some internal planning and noted that last summer, they extended the eligibility timeframe for students to receive vaccines under the publicly funded program. [redacted] ON has also provided some general guidance for HCPs to emphasize the importance of routine immunizations. PHO added that there are some health services research teams that are trying to quantify this, but one of the challenges is that ON's registry is populated by public health units following up with families. Given the current demand on public health units as a result of COVID-19, if a child is not up to date in the registry, it is hard to know if that is really accurate or not.

Q2 – ON believes they are sticking with the 4 month interval for HCWs.

MB replied as follows:

Q1 – MB confirmed that they've seen some decreases in uptake due to delays or suspensions of some of their immunization programs. MB has sent guidance to HCPs to continue to immunize and have heard that some public health units have paused doing childhood immunizations until they are able to get back up and running.

Q2 – If an individual received their first dose before the new recommendation came into effect, MB is honouring the second dose at the 21-28 day interval.

SK replied as follows:

Q1 – SK has had a slight decrease in childhood immunizations and they continue to offer programs for infants and pre-school aged children however the school-age programs depend on whether schools are in or not. SK is also inviting families to come to the public health office with their school-age children.

Q2 – SK noted that they raised this question and that their CMOH asked if they could bring this question for discussion as they are hearing of some HCWs who are saying that HCWs are receiving their second dose at the 21-28 day interval in other PTs.

AB replied as follows:

Q1 – [redacted]

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Q2 – Most HCWs would have received their second doses on schedule, but second dose appointments that were booked before March 10, 2021 were honoured because the informed consent form included that interval. Everyone else is receiving the second dose at the 4 month interval.

BC replied as follows:

Q1 – BC noted that they raised this question and would be following up with some members to discuss strategies. In BC, they are hearing that early childhood and infant schedules (apart from the 2 and 12 month doses) are likely getting delayed. BC noted that it has been a struggle to look at this data because all of their analytic resources have been deployed to the COVID-19 response. Catch up will be required for school-aged vaccination in subsequent years.

Q2 – When BC made the decision to move to the 4 month interval, there was no honouring of booked appointments for second doses therefore HCWs are receiving the second dose at 16 weeks.

NT replied as follows:

Q1 – NT commented that at the beginning of the pandemic, there was a bit of a decline but since then, they have done some catch-up clinics and there is currently no decline as clinics are very busy and everything is on track.

NU replied as follows:

Q1 – NU is not aware of any declines in vaccination programs over the course of the pandemic and noted that they have the benefit of having 25 fly-in communities and can therefore isolate communities with outbreaks. For the most part their vaccination programs have still been running pretty well.

Next meeting: April 22, 2021

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Pan-Canadian Public Health Network
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Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
April 8, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T
NL:
PE:
NS:
NB:
QC:
ON:
MB:
SK:
AB:
BC:
NU:

Invited Participants:
ISC: Mark Sagan
HC/BRDD: Robert Pless
VSWG: Alan Thom
VVWG: Amanada Shaw,
CIRC: Nicolas Gilbert,
DND: Marie-Christine Lamontagne
CSC: Jennifer Morse
PHAC: Natalia Abraham, Chris Hillier
Health Canada: Sophie Sommerer

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed members and encouraged members to submit any questions for Janssen to the CIC Secretariat by end of day April 14, 2021, in advance of their presentation to CIC/VSWG on April 20, 2021. Erin (CIC Federal Co-Chair) also advised members that the CIC Secretariat circulated the link to NACI's statement on extended dose intervals for COVID-19 vaccines, which was posted online on April 7, 2021. Erin (CIC Federal Co-Chair) noted that the uptake from the technical briefing, which included NACI's chair and vice-chair as well as (BC) and (NB), was generally really good and the fact that NACI and PTs went out at the same time showed solidarity.

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2. COVID-19 Vaccination Coverage Update

Nicolas Gilbert (CIRC Federal Co-Chair) provided a COVID-19 vaccination coverage update based on reports that were submitted by PTs on April 6, 2021. Nicolas (CIRC Federal Co-Chair) noted that progress has slowed in the territories, and was interested to know the perspectives of the territories with regards to whether they are reaching a ceiling for uptake, or if all those who wanted to receive a vaccine have already received one. Nicolas (CIRC Federal Co-Chair) noted that PHAC has some public opinion research on Canadians' intent to get the COVID-19 vaccine, however, there were not enough individuals from the territories included in the survey to get a good picture of individuals' intent to receive the COVID-19 vaccine in the territories only.

NU commented that they are looking to survey the communities and inquire about barriers to uptake, and offered to share any results with CIC members.

Nicolas (CIRC Federal Co-Chair) informed members that based on data from the Canadian Community Health Survey collected from September to December 2020, which indicated that 82.5% of seniors aged 65 years and older intended to get vaccinated against COVID-19, and data from PHAC's seasonal influenza vaccination coverage survey collected in January and February 2021, which indicated that 78% of seniors aged 65 years and older intended to get vaccinated against COVID-19, Canada is approaching the percentage of individuals that intended to get vaccinated in this age group.

3. COVID-19 Vaccine Safety Update

Amanda Shaw (VWWG Federal Co-Chair) informed members that 182 AEFIs have been reported since the last update, and that the majority continue to be in females. One death was reported since the last update. Of all the deaths that have been reported to date, 16 have been determined to not be causally linked to the vaccine and the other 11 deaths remain under investigation. Amanda (VWWG Federal Co-Chair) noted that the AEFI reports likely dropped this week due to Friday being a holiday for most of the country.

Two new figures were presented this week but they will not be included in the on-line report:

- Non-serious AEFI counts and rates by adverse event category (top 10)
- Serious AEFI counts and rates by adverse event category (top 10)

PHAC is hoping to include the number of adverse events by vaccine name in the online report within a couple of weeks.

4. Update on CAEFISS Thrombosis/Thrombocytopenia Cases

Natalia Abraham (PHAC) provided an update on cases of thromboses and thrombocytopenia that have been reported to CAEFISS and the Canada Vigilance Database for COVID-19 vaccines, noting that Canada still does not have any cases of CVST or CVT nor any combinations of thrombosis in the context of thrombocytopenia that have been reported up to the CAEFISS system. Natalia (PHAC) advised members that PHAC is still in a case finding endeavour and is trying to put together an interim case definition which is currently quite broad and doesn't include any restrictions with regards to age or gender.

BC asked if Natalia (PHAC) could outline how the causality process will work. Natalia (PHAC) replied that there would be two main arms of the causality process – the first arm would be on an individual level for each event. PHAC has a team of medical reviewers that will conduct primary and secondary reviews, and PHAC is also looking to revive a causality assessment committee that would take the more

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complicated cases and have a deliberation conducted. Natalia (PHAC) noted that the group at PHAC is the surveillance group that deals with AEFI reports and enters them into the CAEFISS system then classifies them, and that PHAC is setting out a process to be able to identify which cases require review by a causality committee. There is no structure within PHAC to be able to deliberate on whether a vaccine causes an event as this is more under the purview of the regulatory body (Health Canada).

BC commented that through the VWG earlier in the fall, PHAC indicated that it was looking at stepping up an Advisory Committee on Causality Assessment (ACCA), and members have been awaiting further details on how it will operate and what types of events will be reviewed. Susanna Ogunnaike-Cooke (PHAC) replied that PHAC has brought someone on board to lead that process and what it could look like, and PHAC is aiming to put forward something to VWG next week, get their input, then present it to CIC as well. The committee could be used for various conditions and not just the one (VIPIT) that is currently being looked at.

5. Regulatory Update on AstraZeneca and Thrombosis/Thrombocytopenia Reports

Sophie Sommerer (Health Canada) provided a regulatory update on AstraZeneca and thrombosis/thrombocytopenia reports, noting that the safety committee in Europe finalized their recommendations on April 7, 2021 and agreed to update their product information, including making some changes to the text in the warnings and precaution section as well as adding some information to their post-market adverse drug reactions information. The committee also indicated that they will issue a risk communication the week of April 12, 2021, and they will look at some changes to the risk management plan in terms of expectations of the company with regards to monitoring these types of events and collecting additional information to continue to explore the situation.

Sophie (Health Canada) informed members that the UK also released an update and until now, they had not make any changes in terms of production information, but on April 7, 2021, they made some updates to the product information based on cases they received in the UK, and also had some communications about the labelling change as well. In both cases, the regulators have indicated that the benefits of the vaccine continue to outweigh the risks and acknowledge that these are very rare events but that it is important for people to be aware of this potential risk. Sophie (Health Canada) added that the WHO also issued a statement on April 7, 2021 with similar conclusions in that the benefits outweigh the risks but it is important for people to be aware of these reports and the possible links to the vaccine.
On April 8, 2021, Australia's regulatory authority also came out with an update with regards to their product labelling. Sophie (Health Canada) noted that from a regulatory perspective, there haven't been broad changes in terms of recommendations for the use of these vaccines. In the UK and in Australia, their vaccine advisory committees have made some age-specific recommendations – in the UK, they are recommending using other vaccines preferentially in people under 30 years of age and Australia is cutting off use of the vaccine to people under 50 years of age.

From a Health Canada perspective, the department issues Terms and Conditions for AstraZeneca last week, and Health Canada is currently conducting a review of that information as well as information from other regulators. Unlike Europe and the UK, Canada has not received reports that present in the same way, but Health Canada is looking very closely at the information provided by other regulators and what has been provided by the vaccine manufacturer, in addition to looking at the risk management plan and what other mechanisms could be put in place for ongoing monitoring.

NB asked, with respect to the different countries that are updating their product monographs or labels, if this is for one specific manufacturer of AstraZeneca or different manufacturers of the vaccine. Sophie (Health Canada) replied that Europe has access to the AstraZeneca product that is manufactured by AstraZeneca as part of their authorization (this would include different manufacturing sites). The UK has approved the AstraZeneca vaccine, including product that is manufactured by the Serum Institute of

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India (SII). In Canada, those two products (AstraZeneca and COVISHIELD) received separate authorizations, but in the UK they are under the same authorization. The approach Health Canada has taken is because these two vaccines are being treated as comparable/interchangeable, that any action taken against the AstraZeneca product would also be taken against COVISHIELD which is manufactured by SII.

ON asked if and when there will be a revised NACI statement released. Kelsey Young (NACI Secretariat) replied that NACI did recommend to pause the use of the AstraZeneca COVID-19 vaccine in individuals 55 years and younger while they await Health Canada's assessment. Erin Henry (CIC Federal Co-Chair) added that NACI is meeting on April 13, 2021, and could revisit the statement then if Health Canada releases their assessment by then.

6. COVID-19 Vaccine Forecasting Dashboard HHR Module

Chris Hillier (PHAC) provided an overview of the Health Human Resources (HHR) Dashboard planning tool that provides estimates of the level of HHR roles needed to administer the required amount of doses to meet a selected jurisdiction's target of vaccination under different scenarios in different vaccination settings. Chris (PHAC) informed members that the original limit of four users per PT has since expanded and members can send requests for access to christopher.hillier@canada.ca.

7. Roundtable

Members were asked to comment on the following questions:

Q1 – Is your jurisdiction planning to administer Pfizer and/or Moderna COVID-19 vaccines in pharmacies?

Q2 – Is your jurisdiction experiencing any vaccine hesitancy with regards to the COVISHIELD or AstraZeneca COVID-19 vaccines?

NU noted that both questions are not applicable to their jurisdiction.

NL replied as follows:

Q1 – NL is still not utilizing pharmacies for COVID-19 vaccination but is planning to very soon. NL plans on having pharmacies administer Moderna and possible AstraZeneca or COVISHIELD COVID-19 vaccines.

Q2 – NL is not experiencing any issues with vaccine hesitancy with regards to the AstraZeneca vaccine. NL anticipated that they would, but they are currently offering this vaccine to the 55-64 year old age group and clinics are filling up very quickly – they've also heard that some people are showing up at clinics and hoping to get in without having an appointment.

NB replied as follows:

Q1 – NB has sent Moderna COVID-19 vaccines to pharmacies and are starting to send AstraZeneca as well – so far they're quite busy and things are going well.

Q2 – NB doesn't think they're experiencing vaccine hesitancy at this time with regards to COVISHIELD – they believe they may have had some last week due to the vaccine arriving in the same week as the AEFIs were reported.

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NS replied as follows:

Q1 – Pharmacies in NS are receiving Moderna, AstraZeneca, and COVISHIELD COVID-19 vaccines – Pfizer is predominantly being used in clinics but if there are unbooked appointments and a surplus of Pfizer vaccines and pharmacies are able to use it within five days, then they can administer Pfizer as well.

Q2 – NS commented that this week was going very well as they are fully booked for appointments with COVISHIELD and AstraZeneca, and that last week they did have a few no shows following the announcements.

PE replied as follows:

Q1 – PE has not made a decision yet on whether pharmacies will be provided with Pfizer or Moderna COVID-19 vaccines yet – PE has discussed providing these vaccines to pharmacies for second doses in the summer, however, PE haven't put it into policy yet.

Q2 – PE is just rolling out the AstraZeneca COVID-19 vaccine this week so they were unable to comment on whether they are experiencing vaccine hesitancy yet.

QC replied as follows:

Q1 – QC is distributing Moderna COVID-19 vaccines in pharmacies.

Q2 – QC has been seeing vaccine hesitancy but has now opened up several clinics province wide that do not require an appointment. QC noted that they were very popular this morning as there were lineups to get a ticket, but wonders how long the rush will last. QC noted that there were two very mediatized deaths from COVID-19 yesterday – one in a 40 year old without underlying conditions and another in a 16 year old with severe co-morbidities.

ON replied as follows:

Q1 – ON is distributing AstraZeneca COVID-19 vaccines in 698 participating pharmacies across their province.

Q2 – ON noted that anecdotally, there have been a lot of media reports talking about vaccine hesitancy, and that their Minister of Health announced on March 29, 2021 that the province would be studying vaccine hesitancy with respect to AstraZeneca.

MB replied as follows:

Q1 – Right now, only AstraZeneca COVID-19 vaccines are in pharmacies and medical clinics, however, MB is in the process of reviewing whether pharmacies will also administer one of the mRNA vaccines but could not comment on when this would happen, and noted the challenges with securing Moderna volumes which makes it more difficult.

Q2 – MB is seeing some vaccine hesitancy as about 30 clinics and pharmacies in MB have indicated that they do not want to participate in administering the AstraZeneca COVID-19 vaccine.

SK replied as follows:

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Q1 – SK hasn't started with pharmacies yet (start date is April 19, 2021) but will either be providing them with Moderna or Pfizer COVID-19 vaccines.

Q2 – In terms of vaccine hesitancy, SK's first delivery of 15,000 doses of COVISHIELD all went to Regina and the line ups for the drive thru vaccination clinics were six hours long. Right now there drive thru clinics don't have a wait time, however, it's hard to say if this is due to vaccine hesitancy or if the market is saturated for the current age group.

AB replied as follows:

Q1 – AB is doing a mixed model and pharmacies are offering Pfizer, Moderna, and AstraZeneca COVID-19 vaccines. AB just started shipping out AstraZeneca vaccine to pharmacies on April 5, 2021.

Q2 – AB noted that uptake seems OK so far and that they are setting up two large clinics for COVID-19 vaccination in Edmonton and Calgary, however, booking for those clinics hasn't started yet so they are not sure what the uptake will be at those clinics.

BC replied as follows:

Q1 – Pharmacies are offering the AstraZeneca COVID-19 vaccine is there is no plan for them to offer Pfizer or Moderna right now.

Q2 – BC could not comment on how busy clinics are but noted that the hearsay is that people are strategically booking appointments with public health clinics as they don't offer the AstraZeneca vaccine.

Erin Henry (CIC Federal Co-Chair) thanked all members who completed the short mid-year check-in survey for the committee.

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ATIA - 19(1)

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Pan-Canadian Public Health Network
Partners in Public Health

Réseau pancanadien de santé publique
Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
June 3, 2021

- Record of Decision -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (NS)
NL: [redacted]
PE:
NB:
QC
ON
MB
SK:
AB:
BC:
NU:
YK:
NT:

Invited Participants:
ISC: Montana Massicotte
VWWG: Amanda Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
DND: Marie-Christine Lamontagne
CSC: Jennifer Morse
PHAC: Susanna Ogunnaike-Cooke, Natalia Abraham, Bryna Warshawsky

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committee and informed members that the status of the Janssen lot currently in quarantine remains the same – Health Canada continues to await further information from Janssen, Emergent, and the US FDA to complete their review. Members were also informed that a member of the COVID-19 Vaccine Effectiveness Surveillance Program team will be coming to present the latest version of the COVID-19 breakthrough case definition at the next CIC meeting on June 10, 2021.

2. COVID-19 Vaccination Coverage Update

Nicolas Gilbert (CIRC Federal Co-Chair) provided a COVID-19 vaccination coverage update based on vaccinations administered up to and including May 29, 2021. Nicolas (CIRC Federal Co-Chair) informed

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members that ON advised PHAC [redacted]

Starting the week of June 7, 2021, PTs will begin to report coverage for individuals aged 12 years and older. Adults having received at least one dose in the 80+ age group is at 92%, and the 70-79 and 60-69 age groups are over 80%, while all other age groups continue to increase.

3. Update on Myocarditis/Pericarditis Following COVID-19 Vaccination

Natalia Abraham (PHAC) and Susanna Ogunnaike-Cooke (PHAC) provided an update on myocarditis cases in Canada. Natalia (PHAC) noted that Canada uses the Brighton Collaboration case definition for myocarditis, which is a draft definition that includes both myocarditis and pericarditis and doesn't require a biopsy for a confirmed cases. To date, there have been 19 cases of myocarditis following Pfizer vaccination, 4 cases following Moderna vaccination, and 2 cases following AstraZeneca vaccination. Most of the cases have occurred within one month, with the exception of one case that occurred within 94 days following vaccination.

With regards to communications, Susanna (PHAC) reiterated that there are still a lot of unknowns and that to date, no clear association has been established between myocarditis and pericarditis and mRNA vaccines. The NACI Secretariat is working to schedule meetings with Israel and the U.S. CDC to learn more about the data that they currently have. Following these conversations, PHAC will work with PTs to identify any outstanding clinical questions and will potentially look to convene a group of experts in the next couple of weeks to explore this issue. Susanna (PHAC) noted that PHAC has expended the information included in the online weekly AEFI report to inform Canadians that PHAC is aware of this situation and is working collectively with PTs to monitor the issue but at this time, Canada is not seeing higher rates of myocarditis and pericarditis than expected outside of a vaccine context. In addition, PHAC has prepared a communiqué that will be sent out to members on June 3, 2021. Conversations are ongoing as to whether PHAC will add additional information on the Government of Canada's website, beyond what's included in the AEFI report.

QC asked, given there is a group of individuals in the 18-30 year old age group (primarily HCWs) that have received a high proportion of second doses, if there are any plans to try and get retrospective data in that group to see if something can be detected sooner rather than waiting for passive reporting. Susanna (PHAC) replied that the communiqué will be sent to HCPs to inform them of the situation and to ask that they consider myocarditis/pericarditis should an individual present with relevant symptoms. PHAC has not had any conversations yet with PTs or research groups with regards to conducting studies, but Susanna (PHAC) noted that this discussion could be brought to VWG to understand if any PTs have plans to conduct studies or if PHAC should be reaching out to researchers to assist with potential studies. Natalia (PHAC) commented that CANVAS might be conducting a study and advised that PHAC should connect with them.

MB asked if the communiqué is being sent out to HCPs or if PTs are to distribute it out. Susanna (PHAC) replied that the communiqué is being sent to SAC, CIC, and VWG, and PTs are asked to disseminate it to their networks and can also use the wording in the document to inform any other communiqués that they plan on developing. PHAC is also planning to send the communiqué to the CPS and likely other associations as well.

Erin Henry (CIC Federal Co-Chair) informed members that NACI Secretariat will be attending ACIP's safety meeting the week of June 7, 2021, and that Israel will be presenting their data to NACI at their meeting on June 9, 2021, so more information should be forthcoming next week.

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MB asked whether or not there is a relationship between the interval length between the first and second dose and myocarditis/pericarditis. Natalia (PHAC) replied that to her knowledge, the interval between doses in Israel was 21 days, but there is no data for other time intervals.

BC asked if the messaging in the communiqué will be used to stimulate reporting given that it doesn't specifically say that HCPs are encouraged to report these events, and also noted that in terms of criteria for severity, it may not meet some of those criteria. Susanna (PHAC) replied that there is wording in the communiqué that asks HCPs to report to the local health authorities and noted that these directions are not very detailed given that the way reporting is done in each jurisdiction differs.

4. NACI Updated Recommendation on Interchangeability of COVID-19 Vaccines

Bryna Warshawsky (PHAC) provided clarification on NACI's updated recommendation on interchangeability of COVID-19 vaccines, noting that there have been some questions raised about the meaning of "readily available". Bryna (PHAC) informed members that NACI has advised that COVID-19 mRNA vaccines can be interchanged – if both products are available, then the individual should receive the same product that they received for their first dose, however, if only one product is available, then the individual should receive the product that's most readily available.

BC commented that in their province, the recommendation has not been interpreted as highly permissive and they continue to advise HCPs to provide the same product as a best practice.

NB asked what the minimum intervals are for second doses if a different product is being provided for the second dose. Bryna (PHAC) replied that the absolute minimum interval would be 28 days, but the optimal interval depends on which variants are circulating in the community. NS commented that their minimum interval is 21 days for two doses of mRNA vaccine and 28 days for a viral vector vaccine (AstraZeneca) followed by a second dose of mRNA vaccine (based on expert opinion).

AB commented that [redacted]

YK commented that their best practice is always to product match and that the issue for the territory is more operational in nature to ensure that the same product is available.

Kelsey Young (PHAC) confirmed that Bryna's (PHAC) interpretation of the NACI recommendation is correct – if both mRNA vaccines are available at the clinic, then the individual should be provided with the same product that they received for their first dose. Kelsey (PHAC) informed members that more language can be included in the NACI statement to clarify what "readily available" means.

5. Roundtable

Members were asked to comment on the following questions:

Q1 – Individuals have received vaccine out of country which are not authorized for use In Canada. Are PTs recognizing vaccine that is not authorized for use in Canada, and, if so, how are you recording it in your immunization registries?

Q2 – For jurisdictions that are seeing vaccine hesitancy with Moderna – are you conducting any campaigns or do you have any novel ideas to combat this vaccine hesitancy that you could share?

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Q3 – In light of NACI's updated recommendations on COVID-19 vaccine interchangeability:

- When will you begin administering second doses of AstraZeneca and at what interval?
- Will you offer the client a choice between AstraZeneca or mRNA?
- For second doses, can you provide an estimate of how many additional doses of AstraZeneca you will require?
- Which age ranges are eligible to receive a second dose of AstraZeneca in your jurisdiction (based on who AstraZeneca was rolled out to)?

NL replied as follows:

Q1 – NL is not recognizing COVID-19 vaccines that are not authorized for use in Canada, and are currently developing a process for how to enter immunization records for individuals that have received their COVID-19 immunization out of province.

Q2 – NL is not seeing any vaccine hesitancy with Moderna at this time.

Q3 – NL is using an 8-week interval for AstraZeneca and individuals who received a first dose of AstraZeneca are being provided with the information required to make an informed decision for their second dose (option to choose between AstraZeneca or mRNA). NL has yet to start second doses of AstraZeneca – they will commence in a few weeks. NL is unsure if they will require additional doses – it will be dependent on demand and they will monitor uptake. NL has heard that other PTs are seeing around 30% uptake for second doses of AstraZeneca.

PE replied as follows:

Q1 – Similar to NL, PE is not recognizing COVID-19 vaccines that are not authorized for use in Canada, however, if individuals present with a record of having received such vaccines, PE will document it in their registry.

Q2 – PE is not seeing any vaccine hesitancy for Moderna – they have not received enough Moderna doses for this to be seen.

Q3 – PE began second doses of AstraZeneca the week of May 31, 2021, and should know within the next couple of weeks whether they need more doses or not. Second doses of AstraZenena are being provided at an 8-week interval. PE's population increases substantially over the summer months so they suspect that they may require additional AstraZeneca doses for visitors or seasonal workers that come to the island and require a second dose. Individuals who received a first dose of AstraZeneca can choose either AstraZeneca or mRNA for their second dose. PE first started providing AstraZeneca to 18-29 year olds, and those individuals are due for their second dose starting the week of May 31, 2021 – PE is promoting mRNA for the second dose for that age group.

NL asked if there was a possibility that the expiration date for the AstraZeneca doses expiring at the end of June 2021 could be extended following the expiry change of the AstraZeneca doses that were due to expire at the end of May 2021. AB commented [redacted] and were advised to raise the question at CIC to determine if other PTs would be interested in this extension and this information would be provided to Health Canada. Erin (CIC Co-Chair) advised that this question could be sent to Health Canada and brought back next week.

NB replied as follows:

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Q1 – Similar to other PTs, NB is not recognizing COVID-19 vaccines that are not authorized for use in Canada, nor are they entering them into their registry.

Q2 – Vaccine hesitancy for Moderna is an issue in NB. NB's COVID-19 vaccine booking system shows whether a clinic is offering Pfizer or Moderna, whereas those who received a COVID-19 vaccine at a pharmacy were not aware of which vaccine they were receiving in advance. NB is working with their communications team and the public to explain that both mRNA vaccines are comparable, and they have also changed their scheduling system to say that the type of mRNA vaccine being offered at clinics could change.

Q3 – NB is using a 14-week interval for all of their COVID-19 vaccines, but this interval will likely be decreased (based on supply). NB has released a memo for second doses of AstraZeneca – anyone who received AstraZeneca for their first dose and are 55 years of age or older are being offered the choice between mRNA or AstraZeneca for their second dose. Individuals under 55 years of age who received AstraZeneca for their first dose are being offered mRNA as their second dose. NB suspects they will have enough AstraZeneca doses but could not confirm. NB is interested in the possible expiration extension of the AstraZeneca doses expiring at the end of June 2021.

NS replied as follows:

Q1 – NS is putting forth a recommendation to their vaccine expert panel on the evening of June 3, 2021, to recognize WHO's emergency use listing of COVID-19 vaccines as valid. NS recognizes that a soft policy is required in the absence of any guidance that might come from NACI or CATMAT. NS will be recording these vaccines in their registry but are struggling on how to record and validate these vaccines, and how that will impact the work being done on PVC at the federal level.

Q2 – NS is not seeing any vaccine hesitancy with Moderna.

Q3 – NS resumed use of AstraZeneca for second doses on June 1, 2021. Individuals who received a first dose of AstraZeneca can choose either mRNA or AstraZeneca for their second dose, and they will be invited to book their appointment via email between June 13-30, 2021. NS is using a 10-week interval. NS is interested in the possible expiration extension of the AstraZeneca doses expiring at the end of June 2021, as they anticipate that they will not be able to use all of those doses given the quick turnaround required. Demand will need to be monitored in order to determine if additional doses are required. Individuals aged 40-64 years will be eligible to receive a second dose of AstraZeneca.

QC replied as follows:

Q1 – QC's vaccine registry allows users to input any vaccine into the registry, including vaccines received abroad. A process has been put in place for people who received a COVID-19 vaccine abroad where individuals are able to book an appointment to have their information entered into QC's registry. Work is still underway regarding individuals who received vaccines that are not authorized for use in Canada – recommendations are being finalized and QC noted that it would be helpful if CATMAT or a NACI sub-committee could look into this and assist with some of the thinking around this. QC has determined, on a case by case basis, whether individuals who received a vaccine not authorized for use in Canada are considered vaccinated or not. QC stressed that with all of the work being done on PVC, clarification is required on which vaccines Canada will accept and QC hopes that there will be some national harmonization on those measures.

Q2 – QC has anecdotally heard of vaccine hesitancy with Moderna that stemmed from social media messages.

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Q3 – QC has already started providing second doses of AstraZeneca at walk-in clinics. QC is using a minimal interval of 8 weeks, with 12 weeks being the optimal interval and individuals who received a first dose of AstraZeneca can choose either mRNA or AstraZeneca for their second dose. QC could not confirm if they will require additional doses and noted it will be dependent on uptake. Individuals aged 45 years or older will be eligible to receive a second dose of AstraZeneca, as well as some younger individuals who received AstraZeneca for various reasons (e.g. before age breakdown, homebound, allergic to mRNA, or have contraindications to mRNA). QC is recommending that individuals under the age of 45 receive an mRNA vaccine as their second dose, but noted that individuals can receive a second dose of AstraZeneca if there is informed consent and if they really want to receive it.

ON replied as follows:

Q1 – ON's decision is still pending however PHO recommended that individuals who received a complete series of one of the COVID-19 vaccines on WHO's emergency use listing should be considered to have a complete and valid schedule. ON noted there is [redacted]

Q2 – ON has heard from colleagues that there is vaccine hesitancy with Moderna but they are not aware of any promotional materials being used to combat it.

Q3 – ON's news release regarding second doses of AstraZeneca went live the morning of June 3, 2021. ON started providing second doses of AstraZeneca the week of May 24, 2021. ON is using a 12-week interval with the exception of certain individuals with medical conditions who were eligible for a shortened second dose interval of 4 weeks. Individuals who received a first dose of AstraZeneca can choose either mRNA or AstraZeneca for their second dose. Individuals aged 40 years or older or any individuals with an allergy to mRNA vaccines are eligible to receive a second dose of AstraZeneca.

MB replied as follows:

Q1 – MB is creating a generic COVID-19 vaccine product for individuals who received a COVID-19 vaccine that is not authorized for use in Canada to enter into their registry. MB could not confirm whether they are determining whether these records are considered valid or not.

Q2 – MB is seeing vaccine hesitancy with Moderna and have had clients leave the clinic site once they found out they were receiving Moderna. MB's communications team is looking at how to combat this hesitancy including offering the option of having a discussion with a medical professional onsite.

Q3 – MB has already started administering second doses of AstraZeneca based on date of first dose. MB is recommending a 12-week interval and a minimum 8-week interval between AstraZeneca and an mRNA vaccine. MB is recommending that individuals who received a first dose of AstraZeneca receive a second dose of mRNA, but will provide a second dose of AstraZeneca if requested. MB currently has a very limited amount of AstraZeneca doses on hand and initially thought that they would not bring in any additional doses, but noted that it will be dependent on demand. Individuals aged 40 years and older and individuals aged 30-39 years with certain high risk medical conditions are eligible to receive a second dose of AstraZeneca.

SK replied as follows:

Q1 – SK noted that they raised this question and commented that they are not sure how to enter these cases into Panorama. SK would like to have federal guidance on this.

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Q2 – SK is not aware of any vaccine hesitancy with Moderna.

Q3 – SK is starting to administer second doses of AstraZeneca the week of June 6, 2021, based on date of first dose. SK is using an interval of 8-12 weeks and individuals who received a first dose of AstraZeneca can choose either mRNA or AstraZeneca (with informed consent as per NACI's recommendations) for their second dose. SK would require approximately 50,000 additional doses of AstraZeneca if everyone who received a first dose wants AstraZeneca for their second dose. SK will start offering second doses of AstraZeneca to individuals aged 65 and older and will eventually open up eligibility to individuals under 40 years of age (as it was originally offered to this age group and many HCWs under 40 received it).

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – [redacted]

BC replied as follows:

Q1 – BC has agreement from its regions to consider WHO's emergency use listing of COVID-19 vaccines as valid. BC also noted that there are some individuals presenting with verbal confirmation of having received a COVID-19 vaccine out of country, but BC will not accept anything but a documented record, partly due to the concern that the record will turn into a passport of some sort.

Q3 – Dr. Bonnie Henry will be announcing BC's plan for second doses of AstraZeneca on the afternoon of June 3, 2021. Starting June 7, 2021, individuals who received a first dose of AstraZeneca will receive a text or email inviting them to book an appointment for their second dose, and will be asked to read some information first. AstraZeneca will only be available in pharmacies and mRNA vaccines will only be available in mass clinic settings. If these individuals feel that they need to have a conversation with someone regarding their second dose, suggestions on who to speak to are being providing (including BC's 8-1-1 health line). BC could not confirm how many additional doses of AstraZeneca they will require but noted that they are conducting a survey the week of June 7, 2021 to try to gauge what the preference of individuals is for second doses. Individuals aged 18 years and older will be eligible to receive a second dose of AstraZeneca.

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NU replied as follows:

Q1 – NU will not recognize vaccines that are not authorized for use in Canada (including for exemption purposes). This decision may be reconsidered at a later time.

Q2 – NU has not seen any vaccine hesitancy with Moderna to date.

Q3 – Question not applicable to NU.

YK replied as follows:

Q1 – YK has had a few instances where this situation has occurred but they are currently not recognizing COVID-19 vaccines that are not authorized for use in Canada and are not entering any of these vaccines into their registry at this time either.

Q2 – YK noted that there have been a few smaller groups and immunocompromised clients hoping to receive the Pfizer vaccine, but YK has not made it available to adults yet. YK is currently saving their Pfizer allocation for their youth – this might change depending on uptake.

Q3 – Question not applicable to YK.

NT replied as follows:

Q1 – NT has not come across this situation.

Q2 – NT has had good uptake and has not seen a lot of vaccine hesitancy. NT has been doing some walk-in and pop-up clinics in bigger stores to promote uptake and also had a proposal put forward for Indigenous community groups/organizations that they can submit an application for a grant of up to $10,000 to promote vaccine uptake in their communities.

Next meeting: June 10, 2021

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CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
March 25, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE:
NS:
NB:
QC:
ON:
MB:
SK:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Mark Sagan
HC/BRDD: Robert Pless
VSWG: Alan Thom
VVWG: Amanada Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
DND: Marie-Christine Lamontagne
CSC: Jennifer Morse
PHAC: Heather Deehan, Milan Patel, Susanna Ogunnaike-Cooke
Health Canada: Sophier Sommerer
University of Toronto: [redacted]
Pfizer: [redacted]

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed members and reminded the committee to submit any comments on the AEFI form and user guide to the CIC Secretariat by end of day March 25, 2021, and to submit nominations for the PT Co-Chair to the CIC Secretariat by March 31, 2021. Members were informed that PHAC will be hosting a dialogue with clinical experts and the public health/medical community to discuss the current state of knowledge and emerging evidence on the thrombocytopenic thrombosis events that are happening post-vaccination with the AstraZeneca vaccine. Invitees will

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include NACI, CCMOHs, and Monika Naus (CIC PT Co-Chair) will also be invited to attend as the PT co-chair of CIC. The CIC co-chairs will provide a summary of the meeting at next week's CIC meeting.

2. Background Rates for Selected Thromboembolic and Coagulation Disorders in Ontario

[redacted]

Bryna Warshawsky (PHAC) asked [redacted]

[redacted]

3. COVID-19 Vaccine Logistics Update

Milan Patel (PHAC) informed members that, as they may have seen in the new, U.S. and Canadian governments agreed on sharing some AstraZeneca COVID-19 vaccine supply. AstraZeneca's product was approved in Canada on February 26, 2021 for the European supply chain. Given that this new supply is coming from the U.S. supply chain, AstraZeneca was required to submit data to Health Canada for the U.S. production process and this is currently under review. Canada will receive approximately 1.5M doses, which are part of the 20M doses that Canada agreed upon with AstraZeneca in August 2020. Even though this supply is coming from the U.S., these doses are part of the same contact.

There are three lots with expiry dates at the end of May 2021 and end of June 2021. The vials will have the U.S. label, not the global European label, and will not include an expiry date.

AB asked if the expiry date can be found on the box. Milan (PHAC) replied that the expiry date is not on the box or the vial, and that the box has the manufacturing date on it. PHAC does have copies of the U.S. label and vial that will be posted on CNPHI along with the presentation deck following the meeting.

NL asked if PHAC has an expected timeline for PT allocations. Heather Deehan (PHAC) replied that PHAC has prepared allocation tables and an ordering process based on the 1.5M doses, however, PHAC is still awaiting confirmation on several details including delivery into Canada and anticipation of Health Canada approval. PHAC is tracking for today or tomorrow to be able to communicate the allocation tables to members so that PTs can see their allocation per capita.

AB asked for the timeline that Health Canada is working with regarding the approval, and whether they are getting approval before April 2, 2021. Robert Pless (Health Canada) advised that he was currently looking into this.

ON asked if there was any further information about SII and exportation in India. Heather (PHAC) replied that PHAC is tracking this closely in order to be able to understand the export ban and its implications for Canada. PHAC is planning for the second shipment of SII to be delivered in mid-April, however, PHAC is in ongoing discussions with PSPC and GAC to get confirmation on what the export ban means in terms of access to those doses. PHAC is tracking for 316,800 doses of AstraZeneca from the COVAX facility but does not have confirmation on delivery dates as of today. PHAC continues to have conversations with the COVAX facility and AstraZeneca Sweden, and Heather (PHAC) noted that it has been

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challenging due to changes in the EU environment and escalating tensions in terms of securing vaccine supply. As soon as more information becomes available, PHAC will advise members.

NB asked if the is a new DIN for this product. Milan (PHAC) confirmed that the DIN is the same but the manufacturing facility is different than what's already been authorized by Health Canada.

QC asked if the lot numbers are different that the ones in Europe. Milan (PHAC) confirmed that yes, they're manufactured in a different facility.

AB asked where the manufacturing facility is. Milan (PHAC) replied that the manufacturing facility is in Maryland, U.S.

4. AstraZeneca Safety Signal

Natalia Abraham (PHAC) provided an update on progress made with regards to AESI definitions, noting that PHAC has received additional details regarding cases in Europe and has incorporated that information into the definitions. Natalia (PHAC) confirmed that PHAC is using the MEDRA classification system for definitions, which is in the CAEFISS system.

Natalia (PHAC) then provided an update on cases for thrombotic events in Canada, noting that the numbers are still very small and there has only been one case in a person under 70 years old. All cases are still under review so there have not been any conclusions made with regard to causality yet. Susanna Ogunnaike-Cooke (PHAC) added that in all of the cases that PHAC has reviewed, there has not been a combination of thrombosis and low platelets, and that this is the particular piece that has been observed in Europe and that is possibly linked to AstraZeneca.

Sophie Sommerer (Health Canada) informed members that when the AstraZeneca and COVISHIELD products were authorized by Health Canada, they were authorized as separate vaccines but were seen as comparable products. A lot of the clinical data used to support the authorization of the COVISHIELD vaccine came from clinical trials that were conducted with the AstraZeneca vaccine. Sophie (Health Canada) commented that it is important to recognize that at this point, it is the AstraZeneca vaccine specifically that is being used in Europe and associated with the cases that they're reporting. The UK is using both products but they aren't differentiating between the two in their reports. What started out in Europe as a batch-specific issue quickly became a potential concern for AstraZeneca broadly, and, given that, when Health Canada sees a signal with the AstraZeneca vaccine, unless there's reason to believe that it's batch-specific, Health Canada would consider the signal to be relevant to the COVISHIELD vaccine as well. Sophie (Health Canada) noted that Health Canada did proceed with an update to the Product Monograph as well as issued a risk communication to address both vaccines on March 24, 2021. Sophie (Health Canada) also highlighted that Health Canada has received a risk management plan for these vaccines and there's ongoing work being conducted by Health Canada to understand how pharmacovigilance is being conducted internationally. Health Canada is also following up with the companies to determine whether and how Canada will be able to differentiate between the two products as this is proving to be challenging, especially in jurisdictions where this distinction is not being made. Health Canada is interested to know how PTs are capturing this information and how it's being reported, and Sophie (Health Canada) added that when the AstraZeneca vaccine enters the Canadian market, Health Canada won't be able to make assumptions about which vaccine version it is.

AB asked if Health Canada could speak to the process regarding if a request to hold vaccine is sent out. Sophie (Health Canada) replied that under the Interim Order, Health Canada does have the authority to suspend an authorization. To do so, Health Canada would require the grounds to believe that the overall risk-benefit profile of the vaccine is no longer positive. Health Canada would have mechanisms by which they would need to collect information to determine that that was the case, and would have to consider

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the frequency of events being reported as well as the causal linkage of those reports to then determine whether there are ways to minimize those risks or whether that risk-benefit has really shifted in the other direction. Sophie (Health Canada) noted that should Health Canada make that decision, they would be transparent about it so that PTs and Canadians are aware of next steps.

AB asked how fast this process would take. Sophie (Health Canada) replied that Health Canada hasn't been in this situation before to be able to determine the speed at which that would happen. Sophie (Health Canada) added that the suspension of licences are not taken lightly and if there was overwhelming evidence that the risks outweigh the benefits, then Health Canada would certainly take action as quickly as possible. Sophie (Health Canada) also noted that countries in the EU did not implement regulatory suspensions of the vaccine, and that following EMA's review, many of the EU countries resumed use of the vaccine at that time.

BC asked if Health Canada has the data it needs in order to be able to quantify risk from COVID-19 by age and by sex in order to do a quantitative risk assessment. Bryna Warshawsky (PHAC) replied that PHAC has been trying to get some of that data and has done some crude calculations to determine the number of deaths that might be expected.

5. Roundtable

Members were asked to comment on the following questions:

Q1 – Which population(s) is your jurisdiction targeting for the AstraZeneca and Serum Institute of India (COVISHIELD) COVID-19 vaccines?

Q2 – Are other jurisdictions requesting a certain amount of supervised immunization injections for new immunizers to be considered competent and, if so, how many injections are they supervised for?

Q3 – Does your jurisdiction have guidelines to support the use of COVID-19 vaccine for outbreak management?

Q4 – Are any jurisdictions **not** having vaccination clinics over the upcoming holiday long weekend?

NL replied as follows:

Q1 – NL is targeting first responders, teachers, and school staff for the COVISHIELD vaccine.

Q3 – NL does not have guidelines to support the use of COVID-19 vaccine for outbreak management but would be very interested in seeing if other PTs do.

Q4 – NL was not planning to have clinics over the upcoming holiday long weekend, however, they believe this has changed.

NS replied as follows:

Q1 – NS is targeting adults aged 60-64 years for COVISHIELD, but will be opening it up to 50-64 year olds as more supply arrives.

Q2 – NS has put an ask out to their operational colleagues to answer this question.

Q3 – NS does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

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Q4 – NS has not been provided with the vaccine schedule for April 2021 yet so was unable to comment.

PE replied as follows:

Q1 – PE is targeting adults aged 18-29 years that can't work remotely and those in food manufacturing.

Q2 – PE noted that they were not entirely sure of the process as operations takes care of that piece however they believe that they watch injections and check for competency for new immunizers.

Q3 – PE does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

Q4 – PE is unsure about the April schedule for the holiday weekend.

QC replied as follows:

Q1 – The populations listed in the SAC summary are still valid for now.

Q2 – QC does not have a pre-determined number of injections that must be supervised.

Q3 – QC has evidence that immunizing during an outbreak doesn't prevent transmission because it takes too much time to develop a good immune response, especially in LTCFs and in elderly populations. When QC conducted a pilot in December 2020 with two LTCFs in outbreaks, one was toward the end of the outbreak so the outbreak ran its course, and the other was at the beginning of the outbreak and didn't prevent transmission. When QC started immunizing in other types of congregate living settings for the elderly, the advice provided was to first ensure that the outbreak is controlled with various measures and if it was widespread, it might be preferable to wait a bit until vaccines are provided, especially if there's a concern that vaccination activities may contribute to the spread.

Q4 – QC confirmed that they are having clinics over Easter weekend.

ON replied as follows:

Q1 – [redacted]

Q2 – ON was unable to comment.

Q3 – ON referenced the following two documents: Guidance for COVID-19 Immunization in Long-Term Care Homes and Retirement Homes, and COVID-19 Variant of Concern: Case, Contact and Outbreak Management Interim Guidance.

Q4 – ON replied that pharmacies and doctor's offices are providing vaccinations but was unable to confirm whether or not mass vaccination clinics would continue over the Easter long weekend.

MB replied as follows:

Q1 – MB is targeting adults aged 50-64 years with high risk medical conditions.

Q2 – MB offers a micro-credential that all new immunizers need to pass, which includes orientation and supervision for their first shift.

Q3 – MB does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

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Q4 – MB will be vaccinating over the Easter long weekend.

SK replied as follows:

Q1 – SK is targeting adults aged 60-69 years and frontline HCWs 40 years of age and up for COVISHIELD and AstraZeneca.

Q2 – SK has a training site with the health authority and there is a checklist that requires a minimum of five supervised injections.

Q3 – SK does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

Q4 – SK believes they're having vaccination clinics over the holiday weekend.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – Guidance on outbreaks is currently being developed.

Q4 – [redacted]

BC replied as follows:

Q1 – BC advised that they would send the list of target populations to the CIC Secretariat.

Q2 – Typically three injections are observed in the skills checklist.

Q3 – BC does not have guidelines to support the use of COVID-19 vaccine for outbreak management, however, COVISHIELD is being used for outbreak management.

Q4 – BC was unable to confirm if vaccination clinics will be held over the holiday weekend.

YK replied as follows:

Q1 – Question does not apply to YK.

Q2 – YK noted that there is a checklist that immunizers go through.

Q3 – YK posed this question and noted that they don't have guidelines yet but are looking to develop something.

Q4 – YK confirmed that they are doing vaccination clinics over the holiday weekend.

NT replied as follows:

Q1 – Question does not apply to NT.

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Q2 – NT has been primarily having RNs administering vaccine so they would follow normal protocols of observing a minimum of three injections before being unsupervised, and nursing students would be supervised on an ongoing basis when they're administering vaccine.

Q3 – NT does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

Q4 – NT is not having vaccination clinics over the holiday weekend. They have already been providing first and second doses, and are starting to go into remote communities a third time to offer second doses and pick up any first doses. NT is now working on vaccine hesitancy.

NU replied as follows:

Q1 – Question does not apply to NU.

Q2 – NU does have an immunization certification process that travelling nurses need to complete before administering vaccine, and noted that there is not a specific number of supervised injections required however a skills checklist needs to be completed.

Q3 – NU does not have guidelines to support the use of COVID-19 vaccine for outbreak management.

Q4 – NU believes they're having vaccination clinics over Easter weekend.

7.0 Pfizer Redistribution Guidance

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[redacted]

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[redacted]

Erin (CIC Federal Co-Chair) noted that NACI is meeting right now and will be talking about what's happening with this and whether or not they'll change their recommendation.

Next meeting: April 1, 2021

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CANADIAN IMMUNIZATION COMMITTEE TELECONFERENCE
May 13, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Althea House for Erin Henry
P/T Co-Chair: [redacted] (NL)
PE: [redacted]
NS:
NB:
QC:
ON:
MB:
SK:
AB:
BC:
NU:
YK:
NT:

Invited Participants:
ISC: Melanie Knight, Mark Sagan
VSWG: Alan Thom
VWG: Amanda Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
DND: Marie-Christine Lamontagne
CSC: Jennifer Morse
PHAC: Bryna Warshawsky, Susanna Ogunnaike-Cooke

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

1. Member Welcome and Introductions

Althea House (a/CIC Federal Co-Chair) welcomed members and advised the committee that, to date, AB, NS, ON, and MB have all paused or limited the use of AstraZeneca vaccine for first doses. Althea (a/CIC Federal Co-Chair) asked for confirmation that NL also paused the use of AstraZeneca for first doses – NL confirmed that this was correct as of May 12, 2021. BC commented that their plan is to use the vaccine to provide second doses to those who received a first dose of AstraZeneca, but those individuals are not eligible yet based on the interval. QC commented that they are currently working on a press release which is expected to come out by end of day May 13, 2021. Members were reminded to inform the CIC Secretariat if their jurisdiction decides to move in this direction, and the Secretariat will continue to notify members. Members were also advised that Health Canada should have an update to provide regarding the Janssen doses that are currently under investigation by the next CIC/VSWG meeting on May 18, 2021.

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2. COVID-19 Vaccination Coverage Update

Nicolas Gilbert (CIRC Federal Co-Chair) provided a COVID-19 vaccination coverage update based on reports that were submitted by PTs on May 10, 2021. Nicolas (CIRC Federal Co-Chair) informed members that the issue regarding double-counting of individuals who have received two different products has not been resolved yet. PHAC has worked with CIRC members to develop an alternate form which is expected to be implemented by PTs in early June 2021. Members were advised that until PTs transition to the new form, there may be some slight over counting of second doses, however, the number of people having received one dose is deemed to be accurate.

In SK and QC, over 50% of adults have received at least one dose. New this week, the proportion of Canadians having received at least one dose of COVID-19 vaccine was broken down into six age groups (coverage is reported as of April 17, 2021). Coverage rates for the 80+ age group is almost flat (90% of seniors in this age group have received at least one dose), while all other age groups continue to increase.

Nicolas (CIRC Federal Co-Chair) informed members that the number of tables in the full report was reduced and includes graphs for age groups instead of tables, and sought feedback from members on this change. AB and NL both commented that they like this new format.

3. Management of Vaccination Errors

Bryna Warshawsky (PHAC) provided an overview of the updated Management of Vaccination Errors guidance document, which was revised based on feedback received by members. Bryna (PHAC) noted that she was expecting to present the document to NACI today, however, the presentation has been delayed to the week of May 17, 2021. Bryna (PHAC) sought feedback on various aspects of the document, specifically the guidance that remains controversial.

AB commented, [redacted]

QC noted that they currently have a few scenarios whereby individuals received a second dose of Pfizer on day 18, and are uncertain about providing a third dose given it is so close to the 19 day interval. In this particular situation, QC noted that they would likely use the interval already in place (16 weeks) unless the individual has a particular condition such as a dialysis patient or a severely immunosuppressed individual in which case they would use the 28 day interval. QC also commented that it raises concerns from an equity perspective (e.g. providing three doses to one person vs providing a first dose to someone).

AB commented that [redacted]

MB commented that it is difficult to ascertain how much of a dose is given, and noted that when this happens, it is usually due to a chaotic situation where there's movement with the patient-client interaction. Very often in practice, immunizers can't determine with a high degree of certainty how much of a dose was given.

Bryna (PHAC) sought feedback from members on how the committee could come to a consensus on the document, and whether a poll should be done or if the document should be released and PTs can make

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adjustments as required. Althea (a/CIC Federal Co-Chair) suggested that the document be presented to NACI then brought back to CIC for further discussion.

With regards to invalid doses, AB commented that [redacted]

Bryna (PHAC) acknowledged Leanne Coward (PHAC) and Christina Jensen's (PHAC) work in helping to develop the document and encouraged members to send any additional feedback to the CIC Secretariat via email.

4. Vaccine Safety Update: TTS/VITT

Natalia Abraham (PHAC) provided an update on TTS/VITT cases, noting that as of May 12, 2021, there have been 28 reports of TTS in Canada, 18 of which tested positive for PF4 antibodies (the remaining reports are pending PF4 antibody lab results from McMaster). The current rate of VITT in Canada is approximately 1 in 83,000 doses administered but could increase to 1 in 55,000 doses administered depending on the results from the remaining 10 cases.

BC asked a question regarding any knowledge around VITT occurring after the second dose. Natalia (PHAC) replied that the UK has said that there is no correlation that there's a higher risk for VITT for the second dose, but Natalia (PHAC) noted that Canada does not have good line of sight on how many second doses have been administered as Canada's data to date is for first doses.

Bryna Warshawsky (PHAC) commented that the UK releases their data every Thursday and that they've had 6 cases after administering 5.9M second doses, so a rate of approximately 1 in a million second doses administered. As a result, the risk is really low, however, whether that rate will increase over time remains to be unseen.

PHO asked if the 28 reports have been sent through CAEFISS or if those reports also include email notifications of cases that are under investigation. Natalia (PHAC) replied that the 28 cases includes 4 reports that are not in CAEFISS yet but PHAC has been provided with fairly detailed information around these cases and feels confident including them in the case count. Natalia (PHAC) noted that PHAC appreciates the email notifications that are being sent from PTs as it prepares all parties to have a coordinated response. PHO asked if PHAC is using doses administered based on the most current data available or applying a lag to determine the denominator used for rate estimates for AstraZeneca. Natalia (PHAC) replied that no lag is required for COVISHIELD, but that PHAC has inputted a 30 day timeframe to account for the timing for AstraZeneca.

5. Roundtable

Members were asked to comment on the following questions:

Q1 – Are any PTs aware of or considering offering COVID-19 vaccine incentives, specifically in business and tourism industries (e.g. a discount to museums for those who show proof of vaccination)?

Q2 – Are any PTs considering no longer pooling vaccine as vaccine supplies increase?

Q3 – Janssen's Product Monograph specifically states to discard any vaccine remaining in the vial after withdrawing 5 doses. Are any PTs planning to attempt to get bonus doses?

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NL replied as follows:

Q1 – NL is not considering offering incentives at this time.

Q2 – NL is currently not pooling vaccine.

Q3 – NL has not discussed this yet and noted that they haven't decided on how to proceed with the use of Janssen given the current pause of the AstraZeneca vaccine.

NS replied as follows:

Q1 – NS is not considering offering incentives at this time.

Q2 – NS provided guidance to HCPs on how to safely pool vaccine, but it was not indicated that it was a directive that one must pool vaccine – it is the choice of the provider.

Q3 – NS does not have any specific plans on how they'll be using Janssen as of yet.

PE replied as follows:

Q1 – PE is not considering offering incentives at this time.

Q2 – PE does not have a policy for pooling vaccine at this time.

Q3 – PE has not made a decision on how they will use the Janssen vaccine but noted that if they did receive it, they would use any extra doses that can be withdrawn and would not waste any.

NB replied as follows:

Q1 –NB raised this question and noted that their museums are offering a discount for those who are vaccinated. NB questioned whether this was an equity issue.

Q2 – NB will be stopping the practice of pooling vaccine for Pfizer doses in September 2021.

Q3 – NB will not be pooling doses or extracting a sixth dose for the Janssen vaccine.

QC replied as follows:

Q1 – There are some private employers in QC who have started to offer incentives for their employees. In terms of whether QC is considering this at the provincial level, QC noted that all options are on the table to ensure that their province has the highest vaccine coverage that they can obtain. For now, QC is mostly working on communications and health promotion strategies and also reducing barriers to access including outreach clinics. QC has not heard whether or not tourism industries in their province are offering incentives but noted there could be initiatives in the private sector that the province does not have control over.

Q2 – Pooling vaccine is a standard practice in QC therefore they see no reason to stop this practice, even if supply increases, given more people can be vaccinated faster using this practice.

Q3 – QC has not discussed this yet but noted that it would be standard practice to administer all doses that are withdrawn so they don't see why it would be any different for Janssen. QC added that as of May 14, 2021, all individuals over the age of 18 will be eligible to book a vaccine appointment therefore by the

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time that they receive the Janssen product, all individuals will have had the opportunity to book an appointment for an mRNA vaccine.

ON replied as follows:

Q1 – ON is unaware of any initiatives with the exception of one wood products company named EACOM Timber Corp. which is paying employees and contractors at their ON and QC sites $200 for the first dose, $150 for the second dose, or $350 for a single-shot vaccine. The program applies retroactively to December 2020 and will run until the end of 2021.

Q2 – [redacted]

Q3 – ON was unable to comment.

MB replied as follows:

Q1 – MB hasn't offered any incentives at the provincial level but has heard of First Nations groups offering draws for items at their vaccination clinics. MB also noted that in the U.S., Ohio is offering a $1M lottery for anyone who gets vaccinated.

Q2 – MB does not have a vaccine pooling process.

Q3 – MB does not believe there have been any discussions around this but noted that it has been very challenging to withdraw additional doses out of vials, especially for Moderna. If MB is able to withdraw a sixth dose of the Janssen dose they would use it, but added that it is also challenging from an inventory perspective.

SK replied as follows:

Q1 – SK is not aware of any businesses offering incentives and is not offering any incentives at the provincial level.

Q2 – SK noted that their vaccine pooling protocol is an interim measure until they have sufficient vaccine supply, as it is not standard practice in their province.

Q3 – SK noted that they raised this question and given that Janssen's Product Monograph does advise to discard the vial after five doses are withdrawn, they wanted to see what other PTs are planning to do.

AB replied as follows:

Q1 – Students at the University of Lethbridge who are fully immunized by September 9, 2021 are eligible to win one of nine grand prizes of full tuition (worth approximately $3600 each). Other prizes include $500 gift certificates to the school's bookstore.

Q2 – AB [redacted]

Q3 – AB [redacted]

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BC replied as follows:

Q1 – BC is not aware of any incentives.

Q2 – In BC's general vaccine administration guidelines, there are specific circumstances under which vaccines can be pooled from a maximum of three vials, and their policies are not product specific. BC has not specifically discussed withdrawing more that five doses of the Janssen vaccine.

NU replied as follows:

Q1 – NU is not aware of any vaccine incentives at this time.

Q2 – NU does not pool vaccine as a standard practice.

Q3 – Question not applicable to NU.

NT replied as follows:

Q1 – When NT first started rolling out vaccine, they became aware of an NGO offering cash to street-involved people who received their COVID-19 vaccine. NT is unsure whether it was equitable at the time and doesn't believe they offered cash for the second dose. NT has hosted two breakfasts for street-involved people to see if it would increase uptake and noted that the approach was equitable as breakfast was offered to everyone, even if they chose not to accept the vaccine. NT will be rolling this approach out to other communities in the North. NT has heard that Indigenous communities have offered incentives through their community governments but could not confirm any further details.

Q2 – NT does not pool vaccine as a standard practice.

Q3 – Question not applicable to NT.

YK replied as follows:

Q1 – A local brewery in Whitehorse is offering a free beer as an incentive for anyone who receives their first dose. The brewery's slogan for this initiative is "You get the shot, we'll get your chaser".

Q2 – YK does not pool vaccine as a standard practice.

Q3 – Question not applicable to YK.

BC asked whether members were interested in discussing the management of individuals with non-severe allergic reactions within the clinic following a first dose of vaccine (e.g. what is done for future vaccines, use of non-sedative anti-histamines in clinic) and whether any PTs have guidance on the management of anaphylaxis that occurs more than two hours after the vaccine has been administered, given that allergists don't have the capacity to manage all of these cases.

QC commented that some work has been done in their province that can be shared at a future meeting, but noted that it does not involve anti-histamine administration.

BC commented that because the number of individuals who experience these events is too great to for allergists to manage, the Canadian Society of Allergy and Clinical Immunology has updated their guidelines, and noted that there will be implications for these individuals with regards to vaccine passports.

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NL commented that they have been experiencing the same issue with regards to backlogs given that they don't have a large number of allergists in the province. One allergist asked if a working group could be developed to try and alleviate the strain being created by this situation, so NL is just in the process of determining how they can approach this group for their perspective.

MB asked if any PTs are planning to interchange vaccines for second doses or if any PTs are aware of any upcoming evidence regarding interchanging Pfizer and Moderna products. Althea House (a/CIC Federal Co-Chair) noted that NACI has made recommendations on using vaccines from the same platform and that SAC has asked NACI to expand on that advice, which NACI is currently working on. As it stands right now, providing Moderna for the second dose after an individual has received Pfizer for the first dose (and vice versa) is permissible. NACI is awaiting studies from the UK to provide guidance on interchangeability across different vaccine platforms.

MB commented that their logistics team is pushing hard to see if MB can be more than permissive and treat the mRNA vaccines as almost identical (e.g. providing any mRNA vaccine for the second dose would be the default), given challenges related to transport and delivery dates.

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Pan-Canadian Public Health Network
Partners in Public Health

Réseau pancanadien de santé publique
Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE
April 13, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE: [redacted]
NS:
NB:
QC:
ON:
MB:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Melanie Knight, Mark Sagan
HC/BRDD: Robert Pless
VWG: [redacted]
CIRC: Nicolas Gilbert, [redacted]
PHAC: Robert Spencer, Simon Côté, Natalia Abraham, Susanna Ogunnaike-Cooke, Sunny Uppal

CIC Secretariat:
Alison Hunt, Sylvie Deschambault

VSWG Members:
NL: [redacted]
PE
MB
SK
AB
BC
YK
NT
NU

Invited Participants:
PSPC: Marie-Ève Benoit, Christa Baird

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ATIA-16(2)(c) ATIA - 19(1) ATIA-15(1) - I.A ATIA - 20(1)(c)

National Defence: Marie-Christine LaMontagne, Julie Nadeau
Correctional Service Canada: Jennifer Morse

VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committees and informed members that the CIC Secretariat is proposing a monthly rotating co-chair model for CIC given that no nominations were put forward for the position and the Secretariat feels as though this model is the most equitable approach (as per the email that was circulated to members on April 9, 2021). Given that the CIC Secretariat prepares the annotated agenda for the co-chairs, responsibilities would include co-chairing the meetings twice weekly alongside the CIC Federal Co-Chair, and attending a prep meeting prior to starting the monthly rotation. [redacted] (CIC PT Co-Chair) has kindly accepted to continue to be the CIC liaison for NACI for the time being. Members were reminded to send in any comments or concerns regarding this approach to the CIC Secretariat by COB April 16, 2021. Members were also advised that Janssen, who was supposed to present to CIC/VSWG on April 20, 2021, is postponing their presentation in light of the current safety signal as they want to have meetings with the U.S., NACI, and Health Canada before they present to CIC/VSWG.

2. Update on Procurement of 1mL Syringes

Robert Spencer (PHAC) informed the committees that, to date, [redacted] have been allocated and shipped to provinces. [redacted] syringes have departed the [redacted] on April 13, 2021 for all 10 provinces against allocations set by the NOC. [redacted] syringes departed China on April 13, 2021 for [redacted] and will be processed, allocated and distributed before the end of the coming weekend. [redacted] syringes are scheduled to depart China on April 20, 2021 and an additional [redacted] are scheduled to depart China on May 1, 2021.

[redacted]

Robert (PHAC) reminded members that once shipments of syringes have departed the [redacted] for individual provinces, they can be tracked on the Public Health Agency's Control Tower that is refreshed on a daily basis from Monday to Friday.

3. Update on CAEFISS Thrombosis/Thrombocytopenia Cases

Susanna Ogunnaike-Cooke (PHAC) informed members that PHAC was notified late the week of April 5, 2021 of one case of confirmed Thrombosis with Thrombocytopenia Syndrome (TTS) following vaccination with either AstraZeneca or COVISHIELD. The individual is recovering and has gone through the lab testing as per the guidance that has been emerging over the past while. The lab results did confirm it is a similar syndrome to what has been observed in Europe.

Natalia Abraham (PHAC) then presented the proposed surveillance case finding definitions for TTS, and noted that she was seeking feedback from CIC and SAC on whether to include the PF4 antibody status as part of the case definition.

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Bryna Warshawsky (PHAC) asked if a negative PF4 antibody status would rule out a probable case. Natalia (PHAC) replied that she would look into that and added that the confirmatory testing that is done through McMaster is separate from the testing that can be done in a hospital, but that it should potentially be changed to "unknown".

QC commented that they've been using onset between 4 and 20 days of vaccination and that this is also the definition used by ON. QC suggested that the number of days should be identified instead of "within a month" as it may lead to questions if the month is 28, 30, or 31 days in length. QC agreed with Bryna's (PHAC) commented that "probable" seems a bit strong for a PF4 negative antibody status. QC also noted that if the definition is too strict with regards to having received heparin, real cases might be excluded and QC suggested asking a hematologist about this. Natalia (PHAC) replied that PHAC could easily use a number of days for the timeframe (instead of "within a month"), and added that the UK expert panel of hematologists used 28 days. With regards to QC's comment on heparin, Natalia (PHAC) noted that this text comes directly from Brighton Collaboration's draft case definition, however, PHAC could raise this point as they currently have a request for feedback on their draft definition in addition to consulting with Canada on how to deal with previous heparin exposure.

BC asked whether these conditions will be reflected in the reporting form and process for reporting, noting that thrombocytopenia does already have a separate reporting category. Natalia (PHAC) replied that she could take this back to PHAC's AEFI reporting form group and determine the best way to include these conditions once the definition is established.

4. COVID-19 Vaccine Logistics Update

Simon Côté (PHAC) provided the weekly COVID-19 vaccine logistics update, noting that over 11.4M doses of COVID-19 vaccine have been distributed to FPTs. Pfizer deliveries for the week of April 12, 2021 are underway and Moderna deliveries for the same week will start on April 14, 2021. Members were advised of a mishap with AstraZeneca's quality assurance paperwork which resulted in only ON and QC receiving their deliveries the week of April 5, 2021. AstraZeneca deliveries continued the week of April 12, 2021 and were expected to be completed by April 14, 2021.

Three future shipments from Pfizer were added since the previous week's update including the weeks of May 31, June 7, and June 14, 2021. Moderna's doses for the week of April 19, 2021 are expected to be delivered the week of April 26, 2021. Discussions are ongoing with Janssen and PHAC is awaiting confirmation from them before the NOC can provide allocation tables and timelines for those doses.

BC asked if Canada still expects to receive the AstraZeneca product from the Serum Institute of India (SII) given the export ban in India. Heather Deehan (PHAC) replied that PHAC has not received written confirmation on whether or not the export ban will have an impact on expected doses. PHAC has a call scheduled with Verity Pharmaceuticals and SII to get confirmation on the number of doses and expects to have that information by April 14, 2021.

NL asked if the allocation tables for the last three shipments of Pfizer (weeks of May 31, June 7, and June 14, 2021) have been sent to PTs yet. Simon (PHAC) replied that PHAC is currently working on the tables and expects to send them to PTs on April 15, 2021.

5. NACI Timelines for Updates on AstraZeneca and Janssen

Matthew Tunis (NACI Secretariat) informed members that NACI met on the morning of April 13, 2021, to discuss the AstraZeneca program pause that is currently in place, as well as to discuss recommendations for Janssen given that doses will be arriving in Canada soon and there is pressure on the committee to finalize their deliberations. NACI was unable to conclude on April 13, 2021, therefore

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they will meet again on April 15, 2021 to discuss the AstraZeneca program pause. Matthew (NACI Secretariat) noted that NACI is considering all options including removing the age limit and also adjusting the age limit. It is expected that NACI will make a decision on this on April 15, 2021, and that recommendations will follow early the week of April 19, 2021 for AstraZeneca and later the week of April 19, 2021 for Janssen.

BC asked if an update could be provided on what's expected from Health Canada later this week with regards to their assessment of AstraZeneca. Robert Pless (Health Canada) replied that Health Canada is working in parallel with AstraZeneca and Verity Pharmaceuticals to update the Product Monographs (PMs) following Health Canada's Marketed Health Products Directorate's assessment, which was presented to NACI on the morning of April 13, 2021. Robert (Health Canada) noted that there is a very short timeline for Health Canada to issue the updated PMs and that Health Canada is still in discussions with AstraZeneca. AstraZeneca will lead and Verity Pharmaceuticals will follow in terms of language changes in the PM. Matthew (NACI Secretariat) advised members that, unlike last time when the AstraZeneca pause was announced and there was coordinated communication on March 29, 2021 from Health Canada, CCMOHs, and NACI, things will play out differently for this announcement. Health Canada will be announcing their conclusion of their assessment and whatever changes that are made to the PMs sometime the week of April 12, 2021, however, NACI will not make an announcement the same week. This will result in a bit of a timing disconnect as the regulatory announcement will precede NACI's announcement, so Matthew (NACI Secretariat) advised members that it may be advantageous if it is at all possible for PTs to wait for NACI's conclusions before launching their own program. However, Matthew (NACI Secretariat) also noted that this is of course at the discretion of PTs.

QC asked, given that the changes cannot currently be presented to members, if a confidential heads up could be forwarded to the chief MOHs so that they are provided with a bit of lead time if PTs will be required to cancel appointments that are already scheduled as a result of the changes. Matthew (NACI Secretariat) replied that he would discuss if an advanced heads up would be at all possible and added that the SAC meeting on April 18, 2021 would be a good forum to provide that notice.

6. Upcoming FPT Summit

Sunny Uppal (PHAC) informed members that PHAC will be hosting an FPT summit the week of May 3, 2021 to share best practices based on learned experiences from the COVID-19 vaccine roll-out. International colleagues will also be invited to speak to their experiences and lessons learned. Similar to the Rehearsal of Concepts that were held for Phases 1 and 2, the summit will be aimed at an ADM-level of engagement. The first part of the summit will be focused on a presentation from an international country, followed by a Q&A session. For the second part, PHAC wishes to hear from PTs on their experiences and lessons learned, and is also open to suggestions for possible topics. PHAC is seeking four to five PTs that are interested in providing a short five minute presentation on topics related to Phase 2 planning. The official request for presenters will be sent out shortly to FPT leads (Major-General Dany Fortin's counterparts) with a deadline of April 20, 2021. Sunny (PHAC) strongly encouraged PTs to extend this invite to their Indigenous planning partners and advised that he would keep members up to date as the planning evolves.

BC asked what is being sought from CIC members, given that they are not at the ADM-level. Erin Henry (CIC Federal Co-Chair) replied that despite the invite going out at the ADM-level, the hope is that all levels including CIC members and CMOHs will also attend. Erin (CIC Federal Co-Chair) noted that some CIC members could be called upon to present, and that this item was to ensure everyone is aware of this event and can block it off in their calendars.

7. Roundtable

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Before starting the roundtable, Erin Henry (CIC Federal Co-Chair) asked QC if they could provide an update on the open COVID-19 immunization clinics that they recently launched that do no require an appointment, and whether or not the province will continue with this practice. QC commented that the clinics were very busy the first couple of days and over the weekend, but that it has since dwindled down. There are no longer lineups and the clinics are essentially walkthrough clinics with no wait times. QC is now moving to an appointment-based service organization for AstraZeneca, but discussions are ongoing as the province has seen that there was a lot of appetite, interest, and satisfaction from patients that used the open clinic approach. QC also noted that one health unit held a nocturnal clinic on April 10, 2021, which stayed open until midnight and was very popular. The MOH of that region went to get his vaccine during that event. QC confirmed that the open clinics and nocturnal clinic were both for AstraZeneca.

Members were asked to comment on the following questions:

Q1 – With regards to NACI's age recommendation for AstraZeneca (*AstraZeneca COVID-19 vaccine should not be used in adults under 55 years of age at this time*), is your jurisdiction using the vaccine for those aged 54 years who are turning 55 by the end of 2021 (e.g. 1966 year of birth)?

Q2 – Is your jurisdiction using physicians/medical clinics for your COVID-19 immunization program?

Q3 – If your jurisdiction is withdrawing 4 or 7 doses of the Pfizer COVID-19 vaccine, are you still administering those doses (when possibly considering that it could be reconstitution errors and impact of the strength of the dose)?

Q4 – What is the current practice used in your jurisdiction for the disposal / destruction of:

- Expired or otherwise unusable COVID-19 vaccine (e.g. due to cold chain breach; defective product, etc.); and
- Depleted or empty COVID-19 vials and packaging (e.g. cartons).

Q5 – Do you routinely obtain written certificates of destruction for the above disposal and, if not, is this something that would be possible to introduce?

NT replied as follows:

Q1 – Question not applicable to NT.

Q3 – Question not applicable to NT.

Q4 – NT hasn't had any expired or unusable vaccine and was unable to comment further but offered to follow up with their counterpart for more details.

YK replied as follows:

Q1 – Question not applicable to YK.

Q3 – Question not applicable to YK.

Q4 – YK is destroying vials and putting them into sharps containers.

Q5 – YK does not have any kind of written disposal protocols but it would be possible for them to introduce a protocol.

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BC replied as follows:

Q1 – BC noted that there has been a bit of confusion in BC regarding this but that their materials say that if an individual hasn't turned 55 years of age, then they are unable to receive the vaccine. The year of birth approach had been implemented for the age-based rollout in BC.

Q2 – BC is not currently using physicians/medical clinics for their COVID-19 immunization program, however, some physicians are working at the immunization clinics being organized through public health. Physicians are able to work in those settings but are not receiving vaccines to administer at their own clinic or practice.

Q3 – Yes, if immunizers in BC are withdrawing 4 or 7 Pfizer doses from a vial, they are administering these doses. BC added that they have been hearing lately that immunizers are not able to withdraw the 6 doses as per the label, so they've issued another survey to ask for detailed information to determine what's happening and what equipment is being used.

Q4 – BC hasn't established a vaccine disposal process and is currently storing anything they get back right now. BC added that they believe the vials are disposed of in sharps containers (then disposed of through a contract with biohazard) and that vaccines do come back to them when they're expired.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – [redacted]

Q4 – [redacted]

SK replied as follows:

Q1 – Individuals have to be 55 years of age on the day that they receive the AstraZeneca vaccine.

Q2 – SK is just starting to distribute vaccines to physician's offices (not very many at this time) but could not comment on the product being distributed.

Q3 – SK has not heard of immunizers being able to withdraw 7 doses but if immunizers withdraw 4 or 7 Pfizer doses from a vial, they are administering these doses.

Q4 – Individual vials ae being disposed of in sharps containers and SK does have a process in place for reporting wastage so that is being tracked.

Q5 – SK was unable to speak to this but offered to follow up with those specifics offline.

MB replied as follows:

Q1 – Individuals have to be 55 years of age on the day that they receive the AstraZeneca vaccine.

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Q2 –MB is currently distributing AstraZeneca to physicians.

Q3 – MB commented that they raised this question and that they are concerned about dosage given withdrawing 4 or 7 doses could be a result of a reconstitution error.

Q4 – For expired unusable vaccines, MB has a process in place to return those vaccines to the warehouse. Any empty vials go in sharps containers and they have provided direction to destroy boxes or remove labels.

Q5 – MB typically sends everything to Stericycle for destruction and they have confirmed with the company that they can receive written confirmation of destruction if required.

ON was unable to comment on the questions with certainty but provided the following comments for Q2:

Q2 – Like BC, ON has some physicians that are participating in the public health run clinics but ON was uncertain if the physicians are being provided with vaccine to administer at their own clinics.

QC replied as follows:

Q1 – QC commented that there was lots of discussion and heated debates on this topic and in the end, the official position of the CMOH is that individuals born in the year 1966 can receive the AstraZeneca vaccine.

Q2 – Right now, QC is not using physician's officers for clinics, however, retired physicians can come and work in COVID-19 immunization clinics. QC added that any physician could do this but because of other needs including managing COVID-19 cases and other conditions, it's not encouraged to have physicians work full-time in these clinics.

Q3 – As a general recommendation, QC has emphasized many times that the technique for withdrawing doses is very important and red flags should be raised if there are not the right number of doses in vials to ensure proper technique is being used.

Q4 – The disposal of vials is monitored closely by the police captain that accompanies the team to each site. Advice is given to the directors of all sites to ensure they are disposed of securely. It is suggested that a black marker is used on the vials before they are disposed of in the sharps containers. The secure disposal of cartons are also followed closely by the police captain and boxes are torn apart and marked with black marker like the vials.

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From: MacRae, Michelle (PHAC/ASPC) on behalf of CCMOH SECRETARIAT / CMHC (PHAC/ASPC)

Sent: 2021-01-09 2:47 PM

To: [redacted] Nadine Sicard; [redacted] Catherine Elliott; [redacted] Njoo, Howard (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC)

Cc: CCMOH SECRETARIAT / CMHC (PHAC/ASPC)

Subject: Participation in the Vaccine Injury Support Program || Participation au Programme de soutien aux victimes d'une vaccination

Attachments: PSVV Q&R - Jan2021.FR.pdf; VISP Q&A - Jan2021.EN.pdf

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(le français suit)

Dear SAC Members,

On December 10, 2020, the Government of Canada announced its intention to establish a pan-Canadian no-fault vaccine injury support program (VISP) in 2021.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, FPT Deputy Ministers of Health Committee on December 11, 2020, and Health Ministers Meeting on December 17, 2020.

On December 23, 2020, letters were sent from the Public Health Agency of Canada to provincial and territorial Deputy Ministers of Health asking jurisdictions to confirm whether they would participate in a federally led VISP or opt-out and establish their own programs.

Please note that responses have been requested by January 15, 2021 in order to inform program design and the solicitation process for a third party administrator.

Attached for information are answers to a series of questions that have been received from jurisdictions. Should jurisdictions have additional questions, please contact Stephen Bent, Director General of the Centre for Immunization and Respiratory Infectious Diseases at stephen.bent@canada.ca.

Best regards,

SAC Secretariat

Chers membres du Comité consultatif spécial,

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Le 10 décembre 2020, le gouvernement du Canada a annoncé son intention de mettre en place un programme pancanadien sans faute de soutien aux victimes d'une vaccination (PSVV) en 2021.

Les paramètres du PSVV ont été discutés au Comité consultatif spécial fédéral, provincial et territorial (FPT) sur la COVID-19 le 3 décembre 2020, au Comité FPT des sous-ministres de la Santé le 11 décembre 2020, et à la réunion des Ministres de la santé, le 17 décembre 2020.

Le 23 décembre 2020, des lettres ont été envoyées par l'Agence de la santé publique du Canada aux sous-ministres provinciaux et territoriaux de la Santé, demandant de confirmer la participation au programme dirigé par le gouvernement fédéral ou dans le cas échéant, si des programmes seraient établis au niveau provincial/territorial.

Veuillez noter que les réponses ont été demandées avant le 15 janvier 2021, pour informer l'élaboration du programme, ainsi que le processus de sollicitation pour un administrateur tiers.

Vous trouverez ci-joint pour information une série de réponses aux questions reçues des provinces et des territoires. Nous sommes à votre disposition si vous avez des questions additionnelles. Veuillez contacter Stephen Bent, Directeur Général, Centre de l'immunisation et des maladies respiratoires infectieuses à stephen.bent@canada.ca.

Meilleures salutations,

Secrétariat CCS

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PROGRAMME DE SOUTIEN AUX VICTIMES D'UNE VACCINATION

QUESTIONS ET RÉPONSES POUR LES PROVINCES ET TERRITOIRES

Conception du programme et indemnisation

Questions : Y a-t-il des détails supplémentaires disponibles sur ce que le programme couvrira et ne couvrira pas? / Y a-t-il d'autres détails concernant le montant de la compensation offerte? / Quand et comment les demandeurs recevront-ils des renseignements sur leurs demandes?

Réponse : Le gouvernement du Canada utilisera, dans la mesure du possible, le programme québécois d'indemnisation des victimes de vaccins existant comme modèle pour concevoir le programme pancanadien, reconnaissant qu'il ne sera peut-être pas possible de reproduire toutes les caractéristiques.

Le programme fournira un soutien financier pour les coûts non assurés résultant d'une blessure grave et permanente subie suite à l'administration d'un vaccin approuvé par Santé Canada. Des détails supplémentaires concernant le soutien financier seront pris en compte lors du processus de conception du programme.

D'autres éléments de conception du programme, tels que le moment et la manière dont les demandeurs seront informés, ne sont pas encore déterminés.

Calendrier du programme

Question : Existe-t-il un calendrier concernant la durée de ce programme, ou une condition selon laquelle les demandeurs doivent présenter leur demande dans un certain délai?

Réponse : Le Programme de soutien aux victimes d'une vaccination est un programme permanent. Les autorisations et le financement du programme ne s'arrêtent pas.

Une demande de soutien doit être présentée dans les trois ans suivant la date de la vaccination ou du décès.

Soutien des provinces et territoires aux demandeurs du Programme de soutien aux victimes d'une vaccination

Questions : Quelle est la procédure à suivre pour présenter une demande dans le cadre du Programme de soutien aux victimes d'une vaccination? Le gouvernement fédéral s'occupe-t-il du processus ou s'attend-on à ce que les provinces et territoires apportent également un soutien quelconque (par exemple, la vérification de l'immunisation, la déclaration d'un événement indésirable)?

Réponse : L'intention est qu'une tierce partie administre le Programme de soutien aux victimes d'une vaccination, y compris la procédure de demande. Si une tierce partie appropriée ne peut être trouvée, l'ASPC administrera le programme.

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Les provinces et territoires continueront à signaler les effets secondaires suivant l'immunisation par le biais des processus existants. De plus, la collaboration des provinces et territoires pourrait être nécessaire, par le biais des mécanismes existants, si des informations supplémentaires sont requises.

Relation avec le droit d'intenter des poursuites

Question : Y aura-t-il des conditions pour soumettre une demande (par exemple, accepter de ne pas intenter une action civile)?

Réponse : Bien que le demandeur conserve son droit d'engager une action civile, il ne peut prétendre à une indemnisation par le biais du Programme de soutien aux victimes d'une vaccination et d'une procédure judiciaire. L'indemnisation dans le cadre du Programme de soutien aux victimes d'une vaccination devra être versée si une indemnisation est reçue par la suite dans le cadre d'une poursuite.

Communications publiques

Questions : Quelles sont les intentions du Canada en matière de communications publiques sur le Programme de soutien aux victimes d'une vaccination (c'est-à-dire quand, qui et comment)? Les provinces et territoires seront-ils informés à l'avance?

Réponse : Le premier ministre a annoncé publiquement le Programme de soutien aux victimes d'une vaccination à la suite de la réunion des premiers ministres du 10 décembre 2020. D'autres communications publiques suivront lorsque la conception du programme sera terminée au printemps 2021. L'ASPC assurera la liaison avec la table de communication fédérale-provinciale-territoriale du Réseau de santé publique pour aider à coordonner les messages complémentaires au fur et à mesure du déploiement du programme.

Points de décision des provinces et territoires pour l'option de se retirer du Programme

Questions : Les provinces et territoires auront-ils la possibilité de se retirer du programme après le délai initial? / Des détails supplémentaires seront-ils fournis avant la date limite fixée pour se retirer du programme?

Réponse : Il a été demandé aux provinces et territoires d'indiquer avant le 15 janvier 2021 s'ils avaient l'intention de se retirer du programme et d'offrir leur propre Programme de soutien aux victimes d'une vaccination. Les représentants de l'ASPC sont disponibles pour rencontrer les provinces et territoires de façon bilatérale afin de répondre aux questions, au besoin.

L'ASPC établira un accord de contribution de 5 ans avec un administrateur tiers. Les provinces et territoires qui ne se retirent pas initialement auront la possibilité de passer de ce programme à un programme provincial-territorial à la fin de l'accord de contribution initial de 5 ans.

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January 5, 2021

VACCINE INJURY SUPPORT PROGRAM

QUESTIONS AND ANSWERS FOR PROVINCES AND TERRITORIES

Program Design and Compensation

Questions: Are there any additional details available on what the program will and will not cover? / Are there any further details regarding the amount of compensation being offered? / When and how will applicants be notified regarding their claim?

Answer: The Government of Canada will use Quebec's existing vaccine injury compensation program as a model for designing the pan-Canadian program to the extent possible, recognizing that it may not be feasible to duplicate every feature.

The program will provide financial support for uninsured costs resulting from a serious permanent vaccine injury sustained following the administration of a Health Canada approved vaccine. Additional details concerning financial support will be considered during the program design process.

Other program design elements, such as when and how applicants will be notified of their claim, are not yet determined.

Program Timeframes

Questions: Is there a time-frame as to the length of this program, or a condition that applicants would have to apply within a certain time frame?

Answer: VISP is an ongoing program. Program authorities and funding do not sunset.

An application for support must be submitted within three years after the date of the vaccination or date of death.

PT Support to VISP applicants

Question: What is the process to apply for the VISP? Is the federal government handling the process or is there an expectation that the PTs will also provide support in any way (e.g., verification of immunization, reporting of an adverse event)?

Answer: The intention is that a Third Party will administer the VISP, including the application process. If a suitable third party cannot be identified, PHAC will administer the program.

PTs would continue to report AEFIs through existing processes, and collaboration may be sought through existing mechanisms should additional information be required.

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Relationship with the Right to Litigate

Question: Will there be conditions for submitting a claim (e.g. agreeing not to file a civil suit)?

Answer: While the applicant would retain their right to undertake civil action, they would not be eligible to receive compensation through both the VISP program and litigation. VISP compensation would have to be repaid if compensation is subsequently received through litigation.

Public Communications

Questions: What are Canada's intentions for public communication about the VISP (i.e., when, who and how)? Will the PTs be given advance notice?

Answer: The Prime Minister publicly announced the VISP following the First Ministers Meeting on December 10, 2020. Further public communications will follow once the program design is complete in spring 2021. PHAC will liaise with the FPT Public Health Network communications table to assist with the coordination of complementary messaging as the program is rolled out.

PT Decision Points for Opting Out

Questions: Will PTs have an opportunity to Opt-out after the initial deadline? / Will additional details be provided prior to the Opt-out deadline?

Answer: PTs have been asked to indicate by January 15, 2021 if they intend to opt out and deliver their own VISP program. PHAC officials are available to meet with PTs bilaterally to answer questions if requested.

PHAC will be establishing a 5-year contribution agreement with a Third Party administrator. P/Ts who do not opt-out initially will have the ability to transition from this program to a P/T program at the end of the initial 5-year contribution agreement.

ATIA - 23

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From: Dickson, Samantha M (HC/SC)
Sent: 2020-05-28 7:00 AM
To: Namiesniowski, Tina (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC); Beaudoin, Carlo (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC); Thornton, Sally (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Slowey2, Charles (PHAC/ASPC); Dagenais, Eric (IC); Johnstone, Marnie (PHAC/ASPC); Evans, Cindy (PHAC/ASPC); Charos, Gina (PHAC/ASPC); Henry, Erin (PHAC/ASPC)
Cc: Guild, Sara (HC/SC); Paquette2, Susie (HC/SC)
Subject: [redacted]
Attachments:

CANADA'S LEGAL TEAM
L'ÉQUIPE JURIDIQUE DU CANADA

HEALTH LEGAL SERVICES	SERVICES JURIDIQUES DE SANTÉ
May 27, 2020	27 mai 2020

[redacted]

Samantha Maislin Dickson
Executive Director and Senior General Counsel
Directrice exécutive et Avocate générale principale

Samantha Maislin Dickson
Executive Director and Senior General Counsel
Department of Justice
Health Legal Services / Government of Canada
samantham.dickson@canada.ca / Tel: 613-957-3766

Directrice exécutive et Avocate générale principale
Ministère de la Justice
Services juridiques de Santé / Gouvernement du Canada
samantham.dickson@canada.ca / Tél: 613-957-3766

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CONSULT-WITHHELD / CONSULTER-RETENUE

Is(Are) exempted and/or excluded pursuant to section(s)
est(sont) exemptée(s) et/ou exclus en vertu de(s)(l')article(s)

23

The head of a government institution may refuse to disclose any record requested under this Act that contains information that is subject to solicitor-client privilege

Le responsable d'une institution fédérale peut refuser la communication de documents contenant des renseignements protégés par le secret professionnel qui lie un avocat à son client

CONSULT-WITHHELD / CONSULTER-RETENUE

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From: Levesque2, Kaili (HC/SC)
Sent: 2021-01-09 5:49 PM
To: Tam, Dr Theresa (PHAC/ASPC)
Cc: Stewart, Iain (PHAC/ASPC); Fortin2, Dany (PHAC/ASPC); Gagnon, Luc (PHAC/ASPC); Tessier, Jean (HC/SC); Szumski2, Roman (PHAC/ASPC); Romano, Anna (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Joyal, Martin (PHAC/ASPC)
Subject: RE: Deck for COVID Committee

Will add it right now to the mitigation slide. It fits well.

Vaccine Insurance Support Program, right? That's the new name?

Kaili Levesque
613.818.0492

From: Tam, Dr Theresa (PHAC/ASPC)
Sent: 2021-01-09 5:41 PM
To: Levesque2, Kaili (HC/SC)
Cc: Stewart, Iain (PHAC/ASPC) ; Fortin2, Dany (PHAC/ASPC) ; Gagnon, Luc (PHAC/ASPC) ; Tessier, Jean (HC/SC) ; Szumski2, Roman (PHAC/ASPC) ; Romano, Anna (PHAC/ASPC) ; Rendall, Jennifer (PHAC/ASPC) ; Joyal, Martin (PHAC/ASPC)
Subject: Re: Deck for COVID Committee

Where are we at with the vaccine injury support program? Should there be a bullet on that in the deck (I am reading decks on my phone so may have missed this)

Sent from my iPhone

> On Jan 9, 2021, at 16:03, Levesque2, Kaili (HC/SC) <kaili.levesque2@canada.ca> wrote:
>
> Noted and I will tackle these now. Martin is incorporating the changes from you/Steve into the deck, and you'll have both back shortly, with translation to follow tomorrow.
> Merci!
> K
>
> Kaili Levesque
> 613.818.0492
>
> ---
>
> **From:** Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
> **Sent:** 2021-01-09 3:59 PM
> **To:** Levesque2, Kaili (HC/SC) <kaili.levesque2@canada.ca>; Fortin2, Dany (PHAC/ASPC) <dany.fortin2@canada.ca>
> **Cc:** Gagnon, Luc (PHAC/ASPC) <luc.gagnon@canada.ca>; Tessier, Jean (HC/SC) <jean.tessier@canada.ca>; Szumski2, Roman (PHAC/ASPC)

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<roman.szumski2@canada.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Joyal, Martin (PHAC/ASPC) <martin.joyal@canada.ca>
Subject: RE: Deck for COVID Committee

Talking points and very good – just need a tone adjustment
From my work this morning I am now less confident we are on track for Q1 – I think we need plans to support the PTs to scale up now (and certainly will need to do more for Q2 in the next 10 weeks):

- We are confident that the pace of Canada's National Immunization Campaign is progressing and that we are prepared to address potential risks. We anticipate that, as all PTs ramp up their vaccination programs and additional supply becomes available, we will be able to immunize Canadians quickly, safely, and efficiently.

From: Levesque2, Kaili (HC/SC) <kaili.levesque2@canada.ca>
Sent: 2021-01-09 2:56 PM
To: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Fortin2, Dany (PHAC/ASPC) <dany.fortin2@canada.ca>
Cc: Gagnon, Luc (PHAC/ASPC) <luc.gagnon@canada.ca>; Tessier, Jean (HC/SC) <jean.tessier@canada.ca>; Szumski2, Roman (PHAC/ASPC) <roman.szumski2@canada.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Joyal, Martin (PHAC/ASPC) <martin.joyal@canada.ca>
Subject: RE: Deck for COVID Committee

Good afternoon,

Revised deck attached, including Luc's slide.
I have captured all comments but want to flag that the slide with the map of Canada – the COP, slide 8, is really tricky to format- I can't figure out how to include the top and bottom bars.
We'll keep working on it but it does not impede the review of the material so wanted to send.
Also including SPs for the Minister updated to align with the new deck.

Happy to discuss,
K

Kaili Levesque

ATIA - 21(1)(b)

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613.818.0492

From: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
Sent: 2021-01-09 12:59 PM
To: Levesque2, Kaili (HC/SC) <kaili.levesque2@canada.ca>; Fortin2, Dany (PHAC/ASPC) <dany.fortin2@canada.ca>
Cc: Gagnon, Luc (PHAC/ASPC) <luc.gagnon@canada.ca>; Tessier, Jean (HC/SC) <jean.tessier@canada.ca>; Szumski2, Roman (PHAC/ASPC) <roman.szumski2@canada.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>
Subject: Deck for COVID Committee

I have made a lot of changes to the deck, [redacted]

Kaili please help me clean up and improve

Dany I will discus this version with you and your team Monday regarding [redacted]

iain

ATIA - 19(1)

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From: Ponic, Pamela (PHAC/ASPC)
Sent: 2021-01-15 8:38 AM
To: Tam, Dr Theresa (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC)
Cc: Njoo, Howard (PHAC/ASPC); Vaughan, Martha (PHAC/ASPC); Currie, Andrea (PHAC/ASPC)
Subject: RE: FYI - Bloomberg - Norway Warns of Vaccination Risks for Sick Patients Over 80

Flagging that the article Jeannette shared is not about supply, but vaccine safety. Confusing because it's both Norway.

Pamela Ponic
[redacted] (cell)

From: Tam, Dr Theresa (PHAC/ASPC)
Sent: 2021-01-15 8:32 AM
To: Macey, Jeannette (PHAC/ASPC)
Cc: Njoo, Howard (PHAC/ASPC) ; Vaughan, Martha (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Currie, Andrea (PHAC/ASPC)
Subject: Re: FYI - Bloomberg - Norway Warns of Vaccination Risks for Sick Patients Over 80

We have just a a whole range of calls on this.working on holding lines to PTs but minister Annan is now going to be at the modelling session

Sent from my iPhone

> On Jan 15, 2021, at 08:29, Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca> wrote:
>
> For Awareness...
>
> https://www.bloomberg.com/news/articles/2021-01-15/norway-warns-of-vaccination-risks-for-sick-patients-over-80
> World
>
> # Norway Warns of Vaccination Risks for Sick Patients Over 80
>
> By Lars Erik Taraldsen and Naomi Kresge January 15, 2021, 3:12 AM EST *Updated on January 15, 2021, 7:01 AM EST*
>
> - Officials say side effects may have contributed to reactions
> - European regulator flagged challenge of monitoring safety
>
> Norway said Covid-19 vaccines may be too risky for the very old and terminally ill, the most cautious statement yet from a European health authority as countries assess the real-world side effects of the first shots to gain approval.
>
> Norwegian officials said 23 people had died in the country a short time after receiving their first dose of the vaccine. Of those deaths, **13 have so far been autopsied, with the results suggesting that common side effects may have**

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contributed to severe reactions in frail, elderly people, according to the Norwegian Medicines Agency.

> "For those with the most severe frailty, even relatively mild vaccine side effects can have serious consequences," the **Norwegian Institute of Public Health** said. "For those who have a very short remaining life span anyway, the benefit of the vaccine may be marginal or irrelevant."

The recommendation does not mean younger, healthier people should avoid being vaccinated. But it's an early indication of what to watch as countries begin to issue safety monitoring reports on the vaccines. Emer Cooke, the new head of the European Medicines Agency, has said tracking the safety of Covid vaccines, especially those relying on novel technologies such as messenger RNA, would be one of the biggest challenges once shots are rolled out widely.

Allergic reactions have been uncommon so far. In the U.S., authorities reported 21 cases of severe allergic reactions from Dec. 14-23 after administration of about 1.9 million initial doses of the vaccine developed by Pfizer Inc. and BioNTech SE. That's an **incidence of 11.1 cases per million doses**, according to the Centers for Disease Control and Prevention.

Though both Covid-19 vaccines approved so far in Europe were tested in tens of thousands of people -- including volunteers in their late 80s and 90s -- the average trial participant was in his or her early 50s. The first people to be immunized in many places have been older than that as countries rush to inoculate nursing-home residents at high risk from the virus.

Norway has given at least one dose to about 33,000 people, focusing on those considered to be most at risk if they contract the virus, including the elderly.

In France, one frail patient died in a care home two hours after being vaccinated, but authorities said given the patient's previous medical history there is no indication the death was linked to the vaccine. **The French pharmaceutical safety agency on Thursday reported four cases of severe allergic reactions and two incidents of irregular heartbeat after vaccination.**

Representatives for Pfizer and BioNTech didn't immediately respond to requests for comment.

The Pfizer-BioNTech vaccine approved late last year has been used most broadly, with a similar shot from Moderna Inc. approved earlier this month also now being administered.

— With assistance by Rudy Ruitenberg, and Stephen Treloar

Jeannette Macey, BSc, MA, MSc
Senior Public Health Advisor | Conseillère principale en santé publique
Office of the Chief Public Health Officer of Canada | Cabinet de l'Administrateur en chef de la santé publique du Canada
Public Health Agency of Canada | Agence de la santé publique du Canada
Cell : 613-762-9579

ATIA - 19(1)

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From: Tam, Teresa (HC/SC)
Sent: 2020-12-22 1:49 PM
To: CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Cc: Tam, Dr Theresa (PHAC/ASPC)
Subject: RE: FYI to CPHO/PresO: Vaccine Injury Support Program

---

Hi,
I believe your email was meant for Dr. Theresa Tam of PHAC.
Regards,

Teresa Tam
Scientific Evaluator, Health Products and Food Branch
Health Canada/Government of Canada
teresa.tam@canada.ca

Évaluatrice scientifique, Direction générale des produits de santé et des aliments
Santé Canada/Gouvernement du Canada
teresa.tam@canada.ca

From: Begin, Martin (HC/SC) **On Behalf Of** CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2020-12-21 2:13 PM
To: Tam, Teresa (HC/SC) ; Stewart, Iain (PHAC/ASPC)
Cc: Morrissette, Eric (HC/SC) ; Payette, Louise (HC/SC) ; Allison, Catherine (HC/SC) ; Magee, Heather (HC/SC) ; Simoneau2, Chantal (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; Mitchell, Heloise (HC/SC) ; Blanchard2, Julie (HC/SC) ; Bousquet, Jean-Philippe (HC/SC) ; Ghantous, Caline (HC/SC) ; Julien, Julie (HC/SC) ; Begin, Martin (HC/SC)
Subject: FYI to CPHO/PresO: Vaccine Injury Support Program

Good afternoon
We have received a media enquiry about the Pan-Canadian Vaccine Injury Support Program. The reporter is asking for an interview. We will decline and provide the answers below. Content comes mainly from pre-approves messages and will be shared with the journalist by 3 p.m. today.
Thank You
Martin
--
Media/Reporter: Canadian Medical Association Journal, [redacted]
Date received: December 17
Deadline to reporter: December 21
Impact: MEDIUM (2)
Complexity: LOW (3)

1. How the programme will operate, including coordination with the Quebec programme?
The Public Health Agency of Canada is creating a new pan-Canadian no-fault vaccine injury support program in consultation with the provinces and territories. The program will provide financial support to people who receive a serious permanent injury after receiving a vaccine approved by Health Canada. To the extent possible, the regime that has been in place in Quebec for over 30 years will be used as the model for designing a pan-Canadian program, recognizing that it will not be possible to duplicate every feature. The scope of the program is still under discussion with provinces and territories and more details will be announced at a later time.

2. Confirm that this applies to all publicly-funded vaccines and not just COVID vaccines?
The new program will provide access to support for all Canadians in the rare event that a person experiences a serious permanent injury as a result of receiving a vaccine authorized by Health Canada, including COVID-19 vaccines.

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3. How was this pulled together so quickly? There was talk, at least as far back as the 1980s, about the need for such a programme (there was resistance to pertussis vaccine at the time, especially in the U.S., U.K., and Europe), but efforts to devise one weren't successful.

The creation of a vaccine injury support program has been previously identified as an area of importance by the Government of Canada, the provinces and the territories. This program will align Canada with all other G7 countries and many other countries that have national vaccine injury support programs.

4. Why this now? An attempt to reassure the public? Quebec and other vaccine injury compensation programmes have not found that these programmes are significant in overcoming vaccine hesitancy.

Quebec has had a program in place since 1988 and has provided exceptional leadership in this area through its existing program. The vaccine injury support program (VISP) will ensure that all Canadians have access to this type of financial support if they experience a serious permanent injury after receiving a vaccine authorized by Health Canada.

While there is limited data on the impact of a no-fault VISP on vaccine uptake, it is expected that the VISP will positively contribute to Canada's ongoing immunization objectives by providing reassurance to Canadians that financial support will be available in the rare event of serious permanent injury.

Approved by:

Stephen Bent, DG, CIRID (approved)
Eric Morrissette, Chief of Media Relations (approved)
Louise Payette, MRMS Director (approved)
Heather Magee, Director, CPAB (approved)
Cathy Allison, A/DG, CPAB (approved)
Pamela Aung-Thin, ADM, CPAB (approved)
Howard Njoo, A/VP, IDPC (approved)
CPHO/PresO (FYI)

Martin Bégin
Communications Executive, Media Relations | *Gestionnaire des communications, relations avec les médias*
Health Canada and the Public Health Agency of Canada |*Santé Canada et l'Agence de la santé publique du Canada*
Government of Canada | *Gouvernement du Canada*
martin.begin@canada.ca

Martin Bégin
Communications Executive, Media Relations | *Gestionnaire des communications, relations avec les médias*
Health Canada and the Public Health Agency of Canada |*Santé Canada et l'Agence de la santé publique du Canada*
Government of Canada | *Gouvernement du Canada*
martin.begin@canada.ca

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From: Macey, Jeannette (PHAC/ASPC)
Sent: 2021-01-08 10:20 AM
To: Leinan, Valerie (PHAC/ASPC); HC.F Comms_Coordination F.SC; Gearey, Jennifer (HC/SC)
Cc: Tam, Dr Theresa (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Aho, Josephine (PHAC/ASPC); Leung, Teresa (PHAC/ASPC); Clark, Julia (PHAC/ASPC); Shah, Lena (PHAC/ASPC); May-Hadford, Jennifer (PHAC/ASPC); Pennock, Jennifer (PHAC/ASPC); anne-marie.ugnat@hc-sc.gc.ca; Njoo, Howard (PHAC/ASPC); Archibald, Chris (PHAC/ASPC)
Subject: RE: Final Approved CPHO Remarks for Friday January 8th

---

Thanks Valerie and based on the Vaccine Safety Report that I have seen on the IT development link last night and your word version, the vaccine safety report does include the total number of doses administered as of January 1st (115,072), which provides the denominator for the 9 AEFIs reported up to that date, underscoring that these are uncommon events (0.008%), and that the 5 serious AEFIs among these, occur even more rarely (0.004%) per total doses delivered.

Jeannette

From: Leinan, Valerie (PHAC/ASPC)
Sent: 2021-01-08 10:11 AM
To: Macey, Jeannette (PHAC/ASPC) ; HC.F Comms_Coordination F.SC ; Gearey, Jennifer (HC/SC)
Cc: Tam, Dr Theresa (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Killen, Marita (PHAC/ASPC) ; Aho, Josephine (PHAC/ASPC) ; Leung, Teresa (PHAC/ASPC) ; Clark, Julia (PHAC/ASPC) ; Shah, Lena (PHAC/ASPC) ; May-Hadford, Jennifer (PHAC/ASPC) ; Pennock, Jennifer (PHAC/ASPC) ; anne-marie.ugnat@hc-sc.gc.ca; Njoo, Howard (PHAC/ASPC) ; Archibald, Chris (PHAC/ASPC)
Subject: RE: Final Approved CPHO Remarks for Friday January 8th

Hi Jennette,
From the vaccine surveillance side, we are comfortable with the strikeouts. I can confirm that only the vaccine safety report will be going live on infobase today.

Thanks,

Valerie

From: Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>
Sent: 2021-01-08 8:48 AM
To: HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>
Cc: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Aho, Josephine (PHAC/ASPC) <josephine.aho@canada.ca>; Leung, Teresa (PHAC/ASPC) <teresa.leung@canada.ca>; Clark, Julia (PHAC/ASPC) <julia.clark@canada.ca>; Shah, Lena (PHAC/ASPC) <lena.shah@canada.ca>; May-Hadford, Jennifer (PHAC/ASPC) <jennifer.may-hadford@canada.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@canada.ca>; Pennock, Jennifer (PHAC/ASPC) <jennifer.pennock@canada.ca>; anne-marie.ugnat@hc-sc.gc.ca; Njoo, Howard

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(PHAC/ASPC) <howard.njoo@canada.ca>; Archibald, Chris (PHAC/ASPC) <chris.archibald@canada.ca>
Subject: RE: Final Approved CPHO Remarks for Friday January 8th

Good morning – please see the revised CPHO remarks for today.

Changes below incorporate:

- Updates with latest numbers
- Text revisions due to the usual late night last minute directives (delete Vaccine Coverage Report, which will not be posted today) from PCO via comms
  -
  - please check the revised wording (strikeout) below...it is just deletions so I think we are fine but appreciate your confirmation

Data Notes:

- **Updated new variant virus numbers (Total of 12 confirmed by NML yesterday) including 1 more variant detected in AB** (official) but **2 more announced by BC** in their presser yesterday:
  - totals by jurisdiction are now: ON 6; AB 4; BC 3; QC 1
- **Daily new cases / daily new deaths added to numbers table:**
  - yesterday's new cases =8,341 (7-day MA now 7,672); yesterday's new deaths =210 (7-day MA now 136)
  - these increases are not being attributed to data dumps – this is just the fluctuation we've been seeing day over day right now
- **as noted today there will be a total of 9 AEFIs being reported publicly** in the Vaccine Safety Report (data up to January 1st), while the internal preliminary numbers for this week (up to Jan 7th) are currently at 13.

Thanks – call if any questions,
Jeannette

Jeannette Macey, BSc, MA, MSc
Senior Public Health Advisor | Conseillère principale en santé publique
Office of the Chief Public Health Officer of Canada | Cabinet de l'Administrateur en chef de la santé publique du Canada
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From: Macey, Jeannette (PHAC/ASPC)
Sent: 2021-01-07 8:23 PM
To: HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>
Cc: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; May-Hadford, Jennifer (PHAC/ASPC) <jennifer.may-hadford@canada.ca>; Aho, Josephine (PHAC/ASPC) <josephine.aho@canada.ca>; Leung, Teresa (PHAC/ASPC) <teresa.leung@canada.ca>; Clark, Julia (PHAC/ASPC) <julia.clark@canada.ca>; Shah, Lena (PHAC/ASPC) <lena.shah@canada.ca>; Leinan, Valerie (PHAC/ASPC) <valerie.leinan@canada.ca>; anne-marie.ugnat@hc-sc.gc.ca; Pennock, Jennifer (PHAC/ASPC) <jennifer.pennock@canada.ca>; Ogunnaike-Cooke, Susanna (PHAC/ASPC) <susanna.ogunnaike-cooke@canada.ca>; Currie, Andrea (PHAC/ASPC)

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<andrea.currie@canada.ca>

Subject: Final Approved CPHO Remarks for Friday January 8th

Numbers for CPHO statement – Thurs Jan 7		
National Indicator	**Value**	**Cut off Date**
Number of new cases	8,341	Jan 7
Cumulative number of cases	635,134	Jan. 7
Number of active cases	80,288	Jan. 7
Number of new deaths	210	Jan. 7
Cumulative number of deaths	16,579	Jan. 7
7-day MA cases	7,672	Jan. 7
7-day MA deaths	136.4	Jan. 7
7-day MA hosp	4,336	Jan. 7
7-day MA ICU	811	Jan. 7
Test positivity[1]	NA	Dec. 27-Jan. 2
Number of people tested[1]	NA	Dec. 27-Jan. 2

1. Not available because of non-reporting from AB.

FRIDAY - CPHO Remarks – January 8, 2021

Bonjour à tout et à tous. There have been **over 635,000** cases of COVID-19 in Canada, including **16,579** deaths and **over 80,250** active cases across the country. Nationally, the average case count is **at 7,672 new cases** being reported daily over the past week and the number of people experiencing severe illness continues to increase. There are an average of **4,336** individuals with COVID-19 being treated in Canadian hospitals, **over 800** of whom are in critical care, and **136** deaths are being reported each day. Canada continues to monitor for virus variants that may be associated with an increased risk of spread; to date, there have been **14** cases of a variant virus first reported in the UK [ON 6; AB 4; BC 3; QC 1] and **no** reports of other variants of concern, including **none** of a variant first reported in South Africa.

As the rollout of COVID-19 vaccines proceeds across Canada - including during this initial phase to protect those at highest risk of severe outcomes or exposure – keeping Canadians up-to-date with timely, factual information is a top priority. The Public Health Agency of Canada (PHAC) is working closely with provinces, territories, Health Canada regulators and other federal jurisdictions to collect information on COVID-19 vaccination coverage and safety. Starting today, this information will be posted on Canada.ca and updated weekly on Friday afternoons. ~~The vaccine coverage report will include information on COVID-19 vaccines currently approved for use in Canada, along with statistics on the number of vaccine doses administered and percentage of people vaccinated by jurisdiction. In addition,~~ The weekly COVID-19 vaccine safety report will include information on adverse events following immunization (AEFI), which involve any health problem that happens following immunization but is not necessarily caused by the vaccine. Adverse events can range from common mild events such as soreness at the site of injection or a slight fever, to more rare serious events, such as a severe allergic reaction. Canada has a robust vaccine safety monitoring system in place and all serious events will be investigated. As of January 1st, there have been over 115,000 doses of COVID-19 vaccines

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administered across Canada, with 9 adverse events reported. There have been no vaccine safety issues identified to date.

As with any new undertaking, we all have questions. These weekly reports on COVID-19 vaccine safety ~~vaccination~~ aim to provide Canadians with regular access to credible information that will assist them in making informed and confident decisions on vaccination for themselves and their families. As always, I call on healthcare providers to listen to Canadians' questions and concerns and to encourage ongoing dialogue to further support vaccine confidence.

The progress we have made across Canada and around the world on vaccines is inspirational, but everything we've achieved is the result of consistent, persistent and collective efforts – we've worked hard and we've kept up the pace! Though I know were are all eagerly awaiting more hopeful days ahead, we've still got a ways to go. We all need to maintain core public health practices - washing, masking, and spacing away any and all opportunities for COVID-19 to spread. As we wait for our place in the vaccine queue, let's continue to support those who need to be protected most urgently and do our part to help all those working to make vaccines available for all Canadians in the months ahead.

Thank you.

ADD TO WEB VERSION: Read my backgrounder to access more COVID-19 Information and Resources on ways to reduce the risks and protect yourself and others.

Jeannette Macey, BSc, MA, MSc
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From: Allison, Catherine (HC/SC)
Sent: 2020-12-07 12:45 PM
To: Ministerial Services / Services Ministériels (HC/SC); Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Chatigny, Elaine (PHAC/ASPC); Capes, Jennifer (PHAC/ASPC); Torunian, Michael (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); Magee, Heather (HC/SC); HC.F Comms_Coordination F.SC; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC); McLachlan, Kailey (HC/SC); HC.F CPAB ADMO Advisors F.SC; Earley, Jaimie (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Aylward, Brett (HC/SC); Nguyen, Jennifer (HC/SC); Ouellette, Francis (HC/SC); Demaine, Erika (HC/SC)
Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

---

I believe these need to be updated in terms of referring it to VIC vs VIP.
Cathy

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-07 12:20 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
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Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Good afternoon,

Just following up on the attached products for your approval this afternoon if possible, as we're hoping to share with MO/PCO.

Thank you!
Amanda

Amanda Ing
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-04 12:55 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
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ATIA - 23

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Subject: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Good afternoon,

Please see attached comms approach, media lines and web content for your approval by 5pm today, if possible.

Thank you,
Amanda

Issue: In early December 2020 (date TBD), the Public Health Agency of Canada will begin consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program. Although these discussions are meant to be held confidentially, messaging should be prepared in the event that these consultations are disclosed to media. Matters related to vaccine uptake have been dominating the media, and media coverage would be expected in this event. This messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.

Media Lines and Web Approvals:
Simone Gobeil, Mgr (2020-11-30)
Stephen Bent, DG (2020-11-30)
Jennifer Pennock, Dir SED (2020-11-30)
Celia Lourenco, HPFB (2020-12-02)
Kelly Robinson, HPFB (2020-12-02)
Megan Bettle, DG, HPFB (2020-12-02)
[redacted]
Laura Russo, Director, CPAB PCRT (2020-12-01)
Cathy Allison, DG, CPAB vaccine communications (FYI)
Dr Howard Njoo and/or Kim Elmslie (FYI)
Pam Aung-Thin, a/ADM, CPAB (Dec 3, 2020)
HPFB ADMO (Dec 4, 2020)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
Cindy Evans, VP, EM (FYI)

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DMO (FYI)
President/CPHO (pending)
MO (FYI)
PCO (FYI)

Comms Approach Approvals:
Kim Elmslie, VP IDPC (FYI)
Pam Aung-Thin, CPAB ADM (Nov 30, 2020)
EM (Nov 30, 2020)
Kaili Levesque for Patrick Tanguy, VP (Dec 4, 2020)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing

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Please note *emails to Comms_Coordination@canada.ca are monitored from 7am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*

Veuillez noter *que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Communications Approach

Vaccine Injury Compensation Program

Issue:
In early December 2020, the Public Health Agency of Canada will be consulting with provinces and territories on the establishment of a pan-Canadian no-fault vaccine injury compensation (VIC) program.

Considerations:

- Although there is significant coverage surrounding global and Canadian efforts to develop and acquire a COVID-19 vaccine, there is limited coverage and interest in the need for a vaccine injury compensation (VIC) program. Since September, the Public Health Agency of Canada has received two media calls enquiring about a VIC program in Canada.
    - *These outlets (Reuters & Global) can be leveraged in any proactive communications related to the establishment of a VIC program.*

- Implementation of a VIC program would align Canada with 26 other countries that have already implemented a vaccine injury compensation program, including all other G7 countries, thereby removing any disadvantage for negotiations with vaccine manufacturers.
    - *Communications will highlight that F/P/T governments are acting to fulfill their part of the social contract, by compensating people injured to ensure no Canadians is left behind and aligning Canadian policy with that of the global community. However, it will also need to address why Canada has not had a program until now.*

- Safety of a forthcoming COVID-19 vaccine weighs heavily on the minds of Canadians, even those who traditionally consider themselves as vaccine acceptors. Behavioural science research engaging Canadians on vaccines indicates that the majority (76%) of Canadians plan to receive the COVID-19 vaccine, but about half of this plan to delay their immunization. Establishment of a VIC now may factor into Canadians concerns about vaccine safety. However, recent behavioural science testing indicated that learning about a national VIC program **would either have no effect or a positive impact** on intentions to be vaccinated against COVID-19 for a large majority of Canadians, around 87%. Only 13% of survey participants reported that a VIC program would negatively impact their intentions to be vaccinated.
    - *Communications around a newly established VIC program will need to be transparent about the rationale for developing the program, underscore how the program puts Canada on equal footing with other governments and protects Canadians, and remind Canadians about the rarity of adverse events related to vaccination. Ongoing proactive communications related to the safety and regulatory processes in Canada prior to approval of a vaccine will also help mitigate concerns about safety.*

- Industry is expected to welcome and acknowledge the importance no-fault VIC as an appropriate measure to maintain industry investment in pandemic vaccines. The province of Quebec already has a successful no-fault VIC Program.
    - *It may be helpful to engage external experts in explaining why a VIC program is necessary (principle of reciprocity) and does not mean government is anticipating safety issues.*

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- PTs may speak publicly about vaccine compensation once the engagement process begins.
    - *It will be important to signal to Canadians that the federal government is pursuing a VIC program, in consultation with PTs, at the outset of the process.*
    - *It will also be important to emphasize and implement a coordinated communications approach, so that Canadians are receiving consistent messaging from all levels of government on VIC.*

Recommended Approach & Tactics:

A proactive communications approach is recommended that includes:

- Beginning to introduce vaccine injury compensation into communications with Canadians as part of ongoing updates on vaccine procurement and roll-out plans.
- Highlight how VIC puts Canada on an equal playing field with other countries, helps with Canada's competitiveness in accessing vaccines, and ultimately, ensures that no Canadian is left behind in the rare event of an adverse outcome.

Tactic	**Timing**	**Communications products**	**Lead**
Messaging - For PTs - For Ministers' inclusion in remarks - For media	December 1-2	Key messages Qs As	Immunization Strategic Communications
Web presence	Week of November 30	Web content	Immunization Strategic Communications and Digital Communications
Outreach to media who have enquired about VIC	Week of November 30	Media statement/update	Media Relations and Immunization Strategic Communications
Outreach to PTs, including PT Comms	Week of November 30	Share common messages and products	Immunization Strategic Communications and VRAT

Key Messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories.
- Establishing a VIC program is part of Canada's broader vaccine strategy and would help ensuring we remain competitive in accessing new vaccines as they become available.
    - We need Canada to be on an equal playing field with other countries.

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    - A VIC program would bring Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.

- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help in the rare event that someone should happen to fall ill from an adverse reaction to a vaccine.
    - This is extremely rare—less than one in a million.
- In the rare event that a Canadian were to fall ill, they should not spend their time litigation in court for a settlement—they deserve fair compensation, which this program offers.
- As the scope of this program is under discussion with the provinces and territories, no further details can be disclosed at this time.

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Media Lines –

Vaccine Injury Compensation program

Issue: In early December 2020 (date TBD), the Public Health Agency of Canada will begin consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program.

Web content is being developed to reference these consultations. Messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.

Key messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC), is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories.
- This will strengthen national immunization campaigns by ensuring equitable access/coverage to vaccines for all individuals immunized in Canada.
- All immunization programs are based on the principle of reciprocity. We therefore have a duty to help if someone should happen to fall ill from a serious adverse reaction to a vaccine. This is extremely rare – less than one in a million
- In the very rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement – they deserve fair compensation.
- Establishing a VIC program as part of Canada's broader vaccination strategy and will help ensure that we remain competitive in accessing new vaccines as they become available, and ultimately protect Canadians.
- It also brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.
- As the scope of this program is still under discussion with the Provinces and Territories, no further details can be disclosed at this time.

If pressed on state of FPT discussions:

Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories

Page: 823 of/de 1,581
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are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury compensation (VIC) program

Questions and Answers:

Q1. Does the Government of Canada have confidence in the COVID-19 vaccines for which it has advance purchase agreements?

Vaccines are a critical way to limit the spread of the virus. They are effective and safe for protecting our health, as well as the health of family and community members.
Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target. The department will not authorize any drug or vaccine unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements. Health Canada continues to monitor their safety and effectiveness once they are on the market.

Q2. What is the likelihood of a possible adverse events following immunization?:

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g. muscle aches, bruising, mild headache, etc) to very rare but serious adverse events (e.g. paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and effectiveness of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Q3. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines

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quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

HC has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs in order to ensure they can be sold.

At this time, we cannot disclose details of specific agreements in an effort to protect our negotiating position and commercially sensitive pricing information, as well as to respect confidentiality clauses in our vaccine agreements.

Q4. What will a Vaccine Injury Compensation Program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program, in consultation with the provinces and territories. Establishing a VIC program will strengthen Canada's broader vaccine strategy will help ensure that Canada remains competitive in accessing COVID-19 vaccines and other new vaccines as they become available, and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national VIC programming in place.

As the scope of this program is under discussion with the Provinces and Territories, no further details can be disclosed at this time.

Q5. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization and conducting any necessary testing of samples, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.

While every effort is being made in Canada to expedite COVID-19 vaccine development, safety, efficacy and quality will not be compromised. COVID-19 vaccine(s) will be subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

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Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q6. How can Canadians be sure the vaccine will be safe if we don't have the same 10-year period as with other vaccines?

The 10-year timeline that is often quoted as the time required to develop a vaccine reflects sequential steps of pre-clinical development and separate phases of clinical trials, as well as the time needed for vaccine manufacturers to fund trials and develop their manufacturing processes. Significant research and development funding is allowing vaccine developers to greatly accelerate their processes.

The use of adaptive clinical trials, which allow ongoing assessment of data and moving from one phase to the next without large gaps, allows more rapid collection of data from clinical trials.

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization and conducting any necessary testing of samples, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available. This ensures that we can expedite the process while maintaining high standards of safety, efficacy and quality.

After a vaccine is granted market authorization, Health Canada and the Public Health Agency of Canada have a joint role in monitoring its safety and effectiveness, along with vaccine manufacturers and provincial/territorial public health authorities. Enhanced monitoring systems will be in place for all COVID-19 vaccines.

Q7. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases.

Addressing vaccine hesitancy is a priority for the Government of Canada. Efforts to inform and educate Canadians to help build vaccine confidence have been part of PHAC's regular business for years.

For example, from 2017 to 2019, the PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant, to debunk misinformation on vaccine safety and importance. PHAC also leads an annual seasonal flu immunization campaign targeting groups, such as seniors over 65

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who are especially vulnerable. A subsequent childhood vaccination campaign will launch early in 2021, with similar goals and objectives to the previous one. Similar communications strategies will be used when a new COVID-19 vaccine is released to ensure that Canadians have the proper information to inform their choice to receive the vaccine when available. These campaigns use different approaches to reach different segments of the public, including advertising, public education and outreach. PHAC works with many partners, including provinces and territories and professional associations to implement these strategies.

The Chief Public Health Officer, Dr. Theresa Tam is also working with chief medical officers of health from all provinces and territories through the Special Advisory Committee and together they will work with public health staff across all jurisdictions in Canada to combat misinformation and concerns around the release of a new COVID-19 vaccine.

DRAFT

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Compensation

- The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program in consultation with the provinces and territories. Establishing a VIC program is part of Canada's broader vaccination strategy and ultimately protect Canadians. It brings Canada in line with its G7 counterparts that all provide VIC protection for a minimum of mandatory vaccines, with most covering all recommended vaccines.-Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs

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From: Bent, Stephen (PHAC/ASPC)
Sent: 2020-12-07 4:29 PM
To: Robinson, Kerry (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); Aung-Thin, Pamela (HC/SC); Romano, Anna (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC)
Cc: Rendall, Jennifer (PHAC/ASPC); Denis, Joel (PHAC/ASPC); Gobeil, Simone (PHAC/ASPC); Russo, Laura (HC/SC)
Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

---

Hi,

Just to add in that CIRID and Policy met with comms today to do further thinking on the comms strategy for this file, and some additional advice on comms approach will be forthcoming.

I think program/policy/comms advice is firming up around recommending that the program is call the Vaccine Injury Support Program - [redacted] This isn't insurance so we can't call it that. Note that most jurisdictions call it Vaccine Injury Compensation Program (US, QC, etc.) …

Iain, we are hoping to brief you soon on the workplan on this file soon once its ready and we've briefed Kim.

Steve

DG, CIRID
IDPC
6138512702

From: Robinson, Kerry (PHAC/ASPC)
Sent: 2020-12-07 4:12 PM
To: Stewart, Iain (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; Aung-Thin, Pamela (HC/SC) ; Romano, Anna (PHAC/ASPC) ; Elmslie, Kim (PHAC/ASPC)
Cc: Rendall, Jennifer (PHAC/ASPC) ; Bent, Stephen (PHAC/ASPC) ; Denis, Joel (PHAC/ASPC)
Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Hi Iain,

Attached is our FPT engagement plan on VIP (now calling it Vaccine Insurance Program?). It does involve using SAC, CDMH and HMM, as well as letters (and bilats with PTs as needed). One thing to note is whether the media lines and information align with the new framing on vaccine insurance or vaccine injury program.

We have started and have completed the bilateral discussion with QC (thank you Howard) and gone to SAC (it went very well, they are pleased to hear of a

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national VIP). I have just updated the timelines for PT engagement.

Kerry

From: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
Sent: 2020-12-07 3:55 PM
To: Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Robinson, Kerry (PHAC/ASPC) <kerry.robinson@canada.ca>; Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>
Cc: Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>
Subject: FW: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

May I see our provincial outreach and engagement plan?

Or is this to be done through CIC / TAC / SAC?

Do we intend to go to FPT DMHealth also HMM?

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-07 12:20 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC

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<hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>
Subject: RE: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Good afternoon,

Just following up on the attached products for your approval this afternoon if possible, as we're hoping to share with MO/PCO.

Thank you!
Amanda

Amanda Ing
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-04 12:55 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC

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<hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>
Subject: For CPHO/President Approval: CA, ML, Web | Vaccine Injury Compensation Program

Good afternoon,

Please see attached comms approach, media lines and web content for your approval by 5pm today, if possible.

Thank you,
Amanda

Issue: In early December 2020 (date TBD), the Public Health Agency of Canada will begin consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program. Although these discussions are meant to be held confidentially, messaging should be prepared in the event that these consultations are disclosed to media. Matters related to vaccine uptake have been dominating the media, and media coverage would be expected in this event. This messaging may also be integrated into remarks made by the Ministers of Health and PSPC in the coming weeks. Those few reporters who have inquired about a VIC program in the past month may also be provided a written update using this messaging.

Media Lines and Web Approvals:
Simone Gobeil, Mgr (2020-11-30)
Stephen Bent, DG (2020-11-30)
Jennifer Pennock, Dir SED (2020-11-30)
Celia Lourenco, HPFB (2020-12-02)
Kelly Robinson, HPFB (2020-12-02)
Megan Bettle, DG, HPFB (2020-12-02)
[redacted]
Laura Russo, Director, CPAB PCRT (2020-12-01)
Cathy Allison, DG, CPAB vaccine communications (FYI)
Dr Howard Njoo and/or Kim Elmslie (FYI)
Pam Aung-Thin, a/ADM, CPAB (Dec 3, 2020)
HPFB ADMO (Dec 4, 2020)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
Cindy Evans, VP, EM (FYI)
DMO (FYI)
President/CPHO (pending)
MO (FYI)
PCO (FYI)

Comms Approach Approvals:
Kim Elmslie, VP IDPC (FYI)
Pam Aung-Thin, CPAB ADM (Nov 30, 2020)
EM (Nov 30, 2020)
Kaili Levesque for Patrick Tanguy, VP (Dec 4, 2020)
President/CPHO (pending)
MO (FYI)
PCO (pending)

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Amanda Ing

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Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856

Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856

Please note *emails to Comms_Coordination@canada.ca are monitored from 7am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*

Veuillez noter *que la boîte de réception comms_coordination@canada.ca est surveillée de 7 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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Call for Applications: Vaccine Injury Support Program

All vaccines used in Canada are regulated by Health Canada and must meet rigorous standards for safety, efficacy and quality before their use is authorized. Vaccinations are administered by trained professionals who follow established protocols. As a result, serious and permanent vaccine injuries are rare in Canada but, as with any medical product, they can occur.

On December 10, 2020, Prime Minister Justin Trudeau announced that the Public Health Agency of Canada will be implementing a pan-Canadian no-fault Vaccine Injury Support Program (VISP).

The VISP will ensure that people in Canada who experience a serious and permanent injury after receiving any Health Canada authorized vaccine have access to financial support. Building on the model that has been in place in Quebec for over 30 years, this pan-Canadian program will ensure fair and equitable access to support for all individuals immunized in Canada.

The Public Health Agency of Canada (PHAC) is pleased to invite eligible organizations to submit an application to administer a no-fault support program for people in Canada with a serious and permanent vaccine injury.

On this page

- Third-party administrator
- Purpose and main elements of the program
- Experience criteria
- Application process and information required
- Deadline for submission

Third-party administrator

A third-party administrator will be selected to administer the VISP via an open solicitation process. Canadian not-for-profit and for-profit organizations and corporations can apply.

The successful applicant will work independently to achieve the program's objectives, based on criteria outlined by the Public Health Agency of Canada. The Public Health Agency of Canada requires that the third-party administrator have experience and expertise in administering similar support programs. Funding to administer the program and manage financial support payments will be provided to the third-party administrator through a 5-year Contribution Agreement with the Public Health Agency of Canada.

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Purpose and main elements of the program

The purpose of the VISP is to ensure that people in Canada have access to financial support in the event that they experience a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada. Main program elements include:

Open and transparent claims intake process –a publicly accessible system for submission of injury claims that clearly outlines the process and eligibility criteria for applicants

Causality assessment –a process that objectively determines a probable causal relationship between injury and vaccine and the degree and duration of disability for the purposes of establishing payments

Administration of financial support payments to beneficiaries –financial support payments to beneficiaries based on a compensation schedule that aligns with accepted industry practices for injury compensation, and is consistent with other public and private sector compensation regimes. Financial support will include income replacement; death benefits; reimbursement of eligible costs such as otherwise uncovered medical expenses; and, injury indemnities.

Appeals process – a process by which applicants can appeal decisions made by the third party, with regards to causality and financial support.

Experience Criteria

The organization must demonstrate how it meets each of the following experience criteria:

- health claim adjudication (including an appeal mechanism);
- experience in injury causality assessments;
- cost-effective delivery in administering payments;
- managing personal information; and,
- providing program delivery at a national level in both official languages.

Application process and information required

The Public Health Agency of Canada's Vaccine Injury Support Program Application Template must be used to submit a funding application. To obtain a copy of the Application Template, please contact: phac.visp-psvv.aspc@canada.ca with the subject line "Application Template - Vaccine Injury Support Program".

Using the template, applicants will be required to provide the following:

- outline of how the organization is able to undertake the proposed program;

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- description of the organization's management structure, governance and financial capacity to carry out the program;
- demonstration of how the organization meets each of the experience criteria;
- detailed information regarding how the organization is able to undertake each of the program elements; and
- detailed information regarding expenses, resources and processes required for the program.

Further guidelines will be included within the template for the application submission.

Applications will undergo a review process. The successful applicant will be awarded funding to administer the VISP.

It is anticipated that a 5-year Contribution Agreement will be signed with the successful applicant. This 5-year period will begin on the date that the agreement is signed by both parties. The initial agreement will end five years after signing but may be extended or renewed, as appropriate.

Applicants with ineligible, incomplete or unsuccessful applications will be notified.

Deadline for submission

The deadline for submitting an Application is 11:59 p.m. PST on February 28, 2021. Complete applications must be submitted to phac.visp-psvv.aspc@canada.ca.

Please note, the Public Health Agency of Canada is under no obligation to enter into a funding agreement as a result of this invitation to submit an application. The Public Health Agency of Canada also reserves the right to reject or accept any submission in whole or in part, as well as cancel and/or re-issue this invitation to submit an application at any time. In addition, the Public Health Agency of Canada will not reimburse costs incurred in the preparation and/or submission of an application.

Application will be acknowledged by email within two business days, so please ensure your email address is included. The Public Health Agency of Canada will update you by email on the status of your submission within 10 business days following the due date of applications.

To obtain additional information about this funding opportunity, please contact phac.visp-psvv.aspc@canada.ca.

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Media Lines

Vaccine Injury Support Program

Issue: In early December 2020, the Public Health Agency of Canada (PHAC) announced that it would establish a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with provinces and territories. To identify a third party administrator for this program, PHAC is launching a solicitation process on February 5, that will run until February 28, 2021.

Previously approved content is highlighted.

Upon Announcement – Key messages:

- As Canadians, we pride ourselves on our commitment to each other. By vaccinating, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories.
- Building on the model in place in Québec for more than 30 years, this will strengthen national immunization campaigns by ensuring fair and equitable access to support all individuals vaccinated in Canada.
- All immunization programs are based on the principle of reciprocity. As such, the Government of Canada is committed to ensuring that Canadians who support public health by being vaccinated are supported should they experience a serious permanent injury as a result of vaccination. This is extremely rare—less than one in a million.
- In the rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement—they deserve fair compensation.
- It also brings Canada in line with its G7 counterparts who all provide vaccine injury support for a minimum of mandatory vaccines, with most covering all recommended vaccines for vaccine preventable diseases.
- A third party is being sought to administer the program, and an open solicitation process is now underway.

If pressed on state of FPT discussions:
Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury support program (VISP), noting that Québec has had a vaccine injury support program since 1988, and will continue to administer its program provincially.

If pressed on timing:
The establishment of a vaccine injury support program has been previously identified as an area of importance by the Government of Canada, the provinces and the territories, to ensure that Canadians who support public health by being vaccinated are supported in the rare event they are injured.

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Questions and Answers:

Q1. What will a vaccine injury support program look like?

The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories. Establishing a VISP will strengthen Canada's broader vaccine strategy and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national vaccine injury support programming in place.

The VISP will ensure that people in Canada who experience a serious permanent injury after receiving any Health Canada authorized vaccine have access to financial support. A suitable Third Party will administer the VISP; if no suitable third party is identified, the program would be federally run and administered by PHAC.

More details on the program and its administration will be available in the coming months.

Q2. Why is the Government of Canada considering using a third party to run the program?

The Government of Canada is seeking to select an experienced third party to administer the program through a contribution agreement. The suitable third party administrator will be able to apply its expertise in administering similar programs that require health claim adjudication and managing personal information as well as delivering a national program in both official languages. The third party will be able to quickly implement and deliver the program in a cost-effective manner.

Q3. Who will this solicitation be open to?

The solicitation is open to Canadian for-profit and not-for-profit organizations and corporations.

Q3. Does the Government of Canada continue to monitor a vaccine's safety after it is authorized?

Canada has a robust and well-established vaccine safety surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Post-market surveillance enables Health Canada to monitor the safety profile of health products once they are marketed to ensure that the benefits of the products continue to outweigh the risks.

Vaccine manufacturers are required to continue to collect information about the long-term safety and effectiveness of their products. Pfizer BioNTech and Moderna, for example, will be following

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clinical trial participants for at least two years after receiving the second dose of the vaccine. Health Canada will continue to review all the available safety data from clinical studies and post-market surveillance and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

Q4. What if an adverse event following immunization is reported?

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g., muscle aches, bruising, mild headache) to very rare but serious adverse events (e.g., paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and efficacy of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

AEFI reports sent to PHAC from FPT jurisdictions are collated into the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Reports of serious adverse events are submitted to PHAC within 7 days of the receipt by the jurisdiction. FPT jurisdictions also notify PHAC of any reports of deaths within 24 hrs of becoming aware of the event. Reports of serious adverse events are processed within 1-2 days of submission and undergo medical case review within 1-3 days of data processing completion. If AEFI counts/rates exceed established background rates/thresholds based on international standards and what was observed during the clinical trials, a safety signal will be issued resulting in various actions. This could include Health Canada and the Public Health Agency of Canada warning Canadians about potential side effects, Health Canada suspending a lot or changing the recommended use of the product, or removing the product from the market.

Commented [KM1]: APPROVED CONTENT on January 7, 2021 via AEFI package

Q5. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

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The Government is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Canada has a robust and well-established vaccine surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

Health Canada will continue to review all the available safety data from ongoing clinical studies and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information.

Q6. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs to ensure they can be sold.

Q7. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing all COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available.

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COVID-19 vaccine(s) are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q8. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases (VPD). Vaccine hesitancy can be attributed to factors related to confidence in vaccines (e.g. safety concerns), complacency (low perceived risk of VPDs), and convenience (difficulty accessing vaccines). The use of social media as an effective tool to spread misinformation and fear about vaccines also plays an important role in vaccine hesitancy.

Addressing vaccine hesitancy is a longstanding priority for the Public Health Agency of Canada (PHAC) but with the arrival of COVID-19, the stakes are higher than in the recent past. Concerted effort is underway with a range of partners to enhance education and guidance, address knowledge and research gaps, and improve coverage data. We are working with healthcare providers to meet the needs of frontline vaccinators and other health professionals who require tools to discuss vaccines with their patients and clients. We are also spearheading a national dialogue to meaningfully engage Canadians on about the importance of COVID-19 vaccines and vaccination more broadly.

This work builds on previous and existing efforts to improve vaccine coverage rates. For example, from 2017 to 2019, PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant as well as to debunk misinformation on vaccine safety and importance. A subsequent childhood vaccination campaign was launched (early 2021), with similar goals and objectives as well as serving as a reminder to parents to ensure children continue to stay up to date on their vaccination schedule. PHAC also leads an annual seasonal influenza immunization campaign targeting groups, such as seniors over 65 who are especially vulnerable.

PHAC is working with many partners to better understand and address vaccine hesitancy related to the new COVID-19 vaccines. These include both internal and external working groups with experts in vaccine hesitancy from different fields of study. This also includes a Vaccine Confidence Task Group made up of multidisciplinary advisors to help develop and provide the tools needed to meaningfully address vaccination questions and concerns. It also involves funding for stakeholders, provinces, territories, and community groups to help them develop tailored approaches that meet their community needs and speak in their community voices. Funding through the Immunization Partnership Fund will be leveraged to ensure Canada's diverse and often underserved groups are taking full advantage of the vaccines available to them.

Commented [KM2]: Program DG approved

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A2021000080

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From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2021-02-03 5:48 PM
To: Ministerial Services / Services Ministériels (HC/SC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Capes, Jennifer (PHAC/ASPC); Torunian, Michael (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC); Wright, Katharine (PHAC/ASPC)
Cc: HC.F Comms_Coordination F.SC; Marchand, Katrina (HC/SC); COVIDvaccineComms / VaccincontrelaCOVIDcommunications (HC/SC); Magee, Heather (HC/SC)
Subject: RE: For CPHO/President Approval: ML, Web Content | Vaccine Injury Support Program

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Good evening,
Apologies for pestering, but we wanted to follow up on this one – since this is linked to a solicitation, we're working with tight timelines and need to flag to MO/PCO today in order to be in a position to post on Friday.
Merci,
Patrick
Patrick Gaebel
Senior Communications Advisor, Ministerial Services | Cell: 416-230-6982
Agent principal des communications, Services ministériels | Cell: 416-230-6982

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2021-02-03 9:39 AM
To: McLeod, Robyn (PHAC/ASPC) ; Macey, Jeannette (PHAC/ASPC) ; Rendall, Jennifer (PHAC/ASPC) ; Killen, Marita (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Currie, Andrea (PHAC/ASPC) ; Charbonneau, Lise (PHAC/ASPC) ; Capes, Jennifer (PHAC/ASPC) ; Torunian, Michael (PHAC/ASPC) ; Wiseman, Vicki (PHAC/ASPC) ; Wright, Katharine (PHAC/ASPC)
Cc: HC.F Comms_Coordination F.SC ; Marchand, Katrina (HC/SC) ; COVIDvaccineComms / VaccincontrelaCOVIDcommunications (HC/SC) ; Magee, Heather (HC/SC)
Subject: RE: For CPHO/President Approval: ML, Web Content | Vaccine Injury Support Program
Good morning,
Just following up on these products. Sorry to pester on this one. We're hoping to get the approved products to MO/PCO today in order to post on Friday.
Thank you,
Amanda
Amanda Ing
(she | elle)
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2021-02-01 2:48 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC)

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<pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>; Wright, Katharine (PHAC/ASPC) <katharine.wright@canada.ca>

Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Filipps2, Lisa (HC/SC) <lisa.filipps2@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Clarke, Nicola (HC/SC) <nicola.clarke@canada.ca>

Subject: For CPHO/President Approval: ML, Web Content | Vaccine Injury Support Program

Good afternoon,

Please find attached web content and updated media lines for your by 9am tomorrow.

Previously approved content is highlighted in yellow. Also note, that the Solicitation web content is intended for 3rd party organizations and not intended for the general population.

Thank you,

Amanda

Context: On December 10, 2020, the Government of Canada announced that the Public Health Agency of Canada would create a Vaccine Injury Support Program (VISP). The program will provide financial support to people in the rare event that they experience a serious permanent injury after receiving a vaccine approved by Health Canada. On February 5, 2021, an open solicitation, along with targeted outreach to identified organizations will be launched to determine if there are any Canadian organizations interested and have the ability/capacity to deliver this program, while ensuring the selection is fair and transparent.

Approvals:

Patricia Salsbury, Senior Manager, Vaccine Confidence (Q- 9 - January 26)
Erin Henry, Dir, IPPD (Q9 – January 26, 2021)
Gina Charos, DG, CIRID (Q9 – January 26, 2021)
[redacted]
Stephanie Parisien, Director, SPPB (January 27, 2021)
Stephen Bent, VISP, DG (January 27, 2021)
EM and CHOPS (January 28, 2021)
Margot Geduld, Communications Executive, COVID-19 vaccine Comms (January 28, 2021)
Heather Magee, Executive Director, CPAB PCRT (January 29, 2021)
Cathy Allison, DG, CPAB vaccine communications (January 29, 2021)
Pam Aung-Thin, a/ADM, CPAB (FYI)
Jean Tessier, A/Vice-President, Comms, PHAC (January 31, 2021)
Kim Elmslie, VP (February 1, 2021)
HPFB ADMO (FYI)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
DMO (FYI)

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President/CPHO (pending)
MO (FYI)
PCO (pending)
Amanda Ing
(she | elle)
Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada
amanda.ing@canada.ca / Cell: 343-542-1856
Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856
***Please note** emails to Comms_Coordination@canada.ca are monitored from 8am – 10pm during the week and from 9am – 9pm on weekends and holidays. The Ministerial Services inbox is only checked periodically. Please continue to cc Comms_Coordination@canada.ca on all approvals and requests.*
***Veuillez noter** que la boîte de réception comms_coordination@canada.ca est surveillée de 8 h à 22 h du lundi au vendredi, et de 9 h à 21 h les fins de semaine et les jours fériés. La boîte de réception des Services ministériels n'est vérifiée que périodiquement. Pour toute demande et approbation, veuillez continuer de mettre Comms_Coordination@canada.ca en cc.*

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From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-18 12:24 PM
To: Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Chatigny, Elaine (PHAC/ASPC); Capes, Jennifer (PHAC/ASPC); Torunian, Michael (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC); Maidment, Leanne (PS/SP); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); HC.F Comms_Coordination F.SC; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC); Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); HC.F CPAB ADMO Advisors F.SC; Earley, Jaimie (HC/SC); Richer, Andrea (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Aylward, Brett (HC/SC); Nguyen, Jennifer (HC/SC); Ouellette, Francis (HC/SC); Marchand, Katrina (HC/SC); Demaine, Erika (HC/SC)
Subject: RE: For CPHO/President Approval: Web | Vaccine Injury Support Program (VISP)
Attachments: WEB_Vaccine Injury Support Program 2020_12_16_1418.docx; WEB_Vaccine Injury Support Program 2020_12_16_1418-tracked.docx

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Good afternoon,

Please see the attached versions, which include rationale for some of the wording/edits for reference.

These are now DM approved.

Thank you,
Amanda

Amanda Ing
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-18 9:16 AM
To: Tam, Dr Theresa (PHAC/ASPC) ; Stewart, Iain (PHAC/ASPC) ; Njoo,

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Howard (PHAC/ASPC) ; McLeod, Robyn (PHAC/ASPC) ; Macey, Jeannette (PHAC/ASPC) ; Rendall, Jennifer (PHAC/ASPC) ; Killen, Marita (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Currie, Andrea (PHAC/ASPC) ; Charbonneau, Lise (PHAC/ASPC) ; Chatigny, Elaine (PHAC/ASPC) ; Capes, Jennifer (PHAC/ASPC) ; Torunian, Michael (PHAC/ASPC) ; Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC) ; Maidment, Leanne (HC/SC) ; Magee, Heather (HC/SC) ; Allison, Catherine (HC/SC) ; Lafkas, Cathy (HC/SC) ; HC.F Comms_Coordination F.SC ; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) ; Russo, Laura (HC/SC) ; McLachlan, Kailey (HC/SC) ; HC.F CPAB ADMO Advisors F.SC ; Earley, Jaimie (HC/SC) ; Richer, Andrea (HC/SC) ; Gearey, Jennifer (HC/SC) ; Kocent, Marissa (HC/SC) ; Payette, Louise (HC/SC) ; HPOC Communications / COPS (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC ; Aylward, Brett (HC/SC) ; Nguyen, Jennifer (HC/SC) ; Ouellette, Francis (HC/SC) ; Marchand, Katrina (HC/SC) ; Demaine, Erika (HC/SC)
Subject: For CPHO/President Approval: Web | Vaccine Injury Support Program (VISP)

Good morning,

Please see attached web content on the Vaccine Injury Support Program (VISP) for your approval by noon, if possible. We are aiming to post this tomorrow.

Thank you,
Amanda

Issue: In early December 2020, the Public Health Agency of Canada began consulting with provinces and territories on establishing a pan-Canadian Vaccine Injury Support Program (VISP). The attached web content is for promoting the new VISP to Canadians.

Approvals:
Simone Gobeil, Mgr (Dec 12, 2020)
Stephen Bent, DG (Dec 12, 2020)
[redacted]
Megan Bettle, DG, HPFB (Dec 12)
**Web plain language review*
HPOC CHOPS and EM (Dec 13)
Heather Magee, Director, CPAB PCRT (FYI)
Cathy Allison, DG, CPAB vaccine communications (Dec 14)
Dr. Njoo and/or Kim Elmslie (Dec 18, 2020)
Pam Aung-Thin, a/ADM, CPAB (December 16, 2020)
HPFB ADMO (Dec 14, 2020)
Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)
DMO (Dec 18, 2020)
President/CPHO (pending)
MO (FYI)
PCO (pending)

Amanda Ing

Communications Advisor, Ministerial Communications Directorate (Ministerial Services)
Health Canada and the Public Health Agency / Government of Canada

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amanda.ing@canada.ca / Cell: 343-542-1856

Conseillère en communications, Direction des communications ministériels (Services ministériels)
Santé Canada et de l'Agence de la santé publique du Canada / Gouvernment du Canada
amanda.ing@canada.ca / Cell: 343-542-1856

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

Vaccine Injury Support

Canada has very high standards set for vaccine safety.

Health Canada:

- only ~~approves~~ authorizes vaccines in Canada after a thorough and independent review of the scientific evidence
- closely monitors once a vaccine is on the market and can quickly have it removed if safety concerns are identified

It's extremely rare to have a serious reaction to a vaccine. However, a small number of people may experience a serious permanent injury as a result of receiving a vaccine.

On December 10, 2020, the Government of Canada announced that the Public Health Agency of Canada would create a vVaccine iInjury Ssupport pProgram. The program will provide financial support to people in the rare event that they experience a serious permanent injury after receiving a vaccine ~~approved~~ authorized by Health Canada. Provinces and territories are being consulted in the development of this program, and to the extent possible, Quebec's existing program will be used as a model. This program will bring Canada in line with other ~~a growing number of~~ countries that have similar programs.

Commented [KM1]: The "permanent injury" portion needs to be included as this is within the scope of the actual program. Saying "adverse event" is too broad, this would include minor adverse events that are not permanent – some of which may not actually lead to injury. This is beyond the scope of the policy authority for the program

Commented [KM2]: Not in plain language

Commented [KM3]: PM announced

Commented [KM4]: Removed as per plain language review: Wording here needs to stay as is as the gen pop will not understand "a pan-Canadian no-fault" wording

Formatted: Font: (Default) Verdana, Font color: Custom Color(RGB(31,73,125)), Pattern: Clear

Commented [KM5]: For consistency

Commented [KM6]: Link to Quebec program

Commented [KM7]: As per latest language from HMM deck

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https://www.canada.ca/en/public-health/services/vaccination-children/safety-concerns-side-effects.html

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Commented [KM4]: Removed as per plain language review: Wording here needs to stay as is as the gen pop will not understand "a pan-Canadian no-fault" wording

Commented [KM5]: Link to Quebec program

Commented [KM6]: As per latest language from HMM deck

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From: Capes, Jennifer (PHAC/ASPC)
Sent: 2020-12-14 1:22 PM
To: Ministerial Services / Services Ministériels (HC/SC); Rendall, Jennifer (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC); Stewart, Iain (PHAC/ASPC); Njoo, Howard (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Ponic, Pamela (PHAC/ASPC); Currie, Andrea (PHAC/ASPC); Charbonneau, Lise (PHAC/ASPC); Chatigny, Elaine (PHAC/ASPC); Torunian, Michael (PHAC/ASPC); Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC); Maidment, Leanne (HC/SC); Magee, Heather (HC/SC); Allison, Catherine (HC/SC); Lafkas, Cathy (HC/SC); HC.F Comms_Coordination F.SC; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC); Russo, Laura (HC/SC); McLachlan, Kailey (HC/SC); HC.F CPAB ADMO Advisors F.SC; Earley, Jaimie (HC/SC); Richer, Andrea (HC/SC); Gearey, Jennifer (HC/SC); Kocent, Marissa (HC/SC); Payette, Louise (HC/SC); HPOC Communications / COPS (PHAC/ASPC); Eckersley, Jennifer (HC/SC); HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC; Aylward, Brett (HC/SC); Nguyen, Jennifer (HC/SC); Ouellette, Francis (HC/SC); Aung-Thin, Pamela (HC/SC); Demaine, Erika (HC/SC); Marchand, Katrina (HC/SC); Roussy, Alyssa (HC/SC); Lafkas, Cathy (HC/SC); Nahum, Marilyne (HC/SC); McLachlan, Kailey (HC/SC)
Subject: RE: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)
Attachments: PHAC_ML_VISP_2020-12-08_1540 (002)_OP.docx

Good afternoon – apologies for delay. Attached please find the approved MLs – changes tracked. We did not review the Comms approach as it is no longer current given the announcement on Thursday. Apologies if you still require this document – just let us know.
Thanks
Jen

Jennifer Capes
Senior Advisor | Conseillère principale
Office of the President and Chief Public Health Officer | Cabinet de la Présidente et de l'Administrateur en chef de la santé publique
Public Health Agency of Canada | Agence de la santé publique du Canada
130 Colonnade Road, Ottawa, ON K1A 0K9
613-266-4167 | jennifer.capes@canada.ca

From: Ministerial Services / Services Ministériels (HC/SC)
Sent: 2020-12-14 8:33 AM
To: Rendall, Jennifer (PHAC/ASPC) ; Tam, Dr Theresa (PHAC/ASPC) ; Stewart, Iain (PHAC/ASPC) ; Njoo, Howard (PHAC/ASPC) ; McLeod, Robyn (PHAC/ASPC) ; Macey, Jeannette (PHAC/ASPC) ;

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Killen, Marita (PHAC/ASPC) ; Ponic, Pamela (PHAC/ASPC) ; Currie, Andrea (PHAC/ASPC) ; Charbonneau, Lise (PHAC/ASPC) ; Chatigny, Elaine (PHAC/ASPC) ; Capes, Jennifer (PHAC/ASPC) ; Torunian, Michael (PHAC/ASPC) ; Wiseman, Vicki (PHAC/ASPC)
Cc: Hinds, Chris (HC/SC) ; Maidment, Leanne (HC/SC) ; Magee, Heather (HC/SC) ; Allison, Catherine (HC/SC) ; Lafkas, Cathy (HC/SC) ; HC.F Comms_Coordination F.SC ; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) ; Russo, Laura (HC/SC) ; McLachlan, Kailey (HC/SC) ; HC.F CPAB ADMO Advisors F.SC ; Earley, Jaimie (HC/SC) ; Richer, Andrea (HC/SC) ; Gearey, Jennifer (HC/SC) ; Kocent, Marissa (HC/SC) ; Payette, Louise (HC/SC) ; HPOC Communications / COPS (PHAC/ASPC) ; Eckersley, Jennifer (HC/SC) ; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC ; Aylward, Brett (HC/SC) ; Nguyen, Jennifer (HC/SC) ; Ouellette, Francis (HC/SC) ; Aung-Thin, Pamela (HC/SC) ; Demaine, Erika (HC/SC) ; Marchand, Katrina (HC/SC) ; Roussy, Alyssa (HC/SC) ; Lafkas, Cathy (HC/SC) ; Nahum, Marilyne (HC/SC) ; McLachlan, Kailey (HC/SC)
Subject: Re: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)
Good morning,
Just following up on the attached products.
Thanks!

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-11 12:21 PM
To: Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Roussy, Alyssa (HC/SC) <alyssa.roussy@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>
Subject: RE: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)
Good afternoon,

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Apologies for following up again, just wanted to check in on the attached media lines and comms approach. The web content is being re-worked so that can be put on hold for now.
Thank you,
Alicia

Alicia Norng
Communications Officer | Ministerial Services
Agente de communications | Services ministériels
alicia.norng@canada.ca | 613-297-6991

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-10 7:41 PM
To: Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Roussy, Alyssa (HC/SC) <alyssa.roussy@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>
Subject: RE: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)

Good evening,
Apologies for the late email. I just wanted to follow up on these products as the news release is now live: https://www.canada.ca/en/public-health/news/2020/12/government-of-canada-announces-pan-canadian-vaccine-injury-support-program.html
I've included clean and tracked versions so you can see the edits made since these were last approved by President Stewart on December 7th.
The web content is attached for your information.
Thank you very much,
Amanda

Amanda Ing
Communications Advisor | Conseillère en communications

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Tel: 343-542-1856

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-10 3:56 PM
To: Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Roussy, Alyssa (HC/SC) <alyssa.roussy@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>
Subject: RE: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)

Hello,

Thank you for your approval on the news release.

Please see attached the media lines and comms approach for your approval today. I've included clean and tracked versions so you can see the edits made since these were last approved by President Stewart on December 7th.

The web content is attached for your information.

Thank you,

Amanda

Amanda Ing
Communications Advisor | Conseillère en communications
Tel: 343-542-1856

From: Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>
Sent: 2020-12-10 3:06 PM
To: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey,

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Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC) <phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Roussy, Alyssa (HC/SC) <alyssa.roussy@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>
Subject: RE: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP) Approved by the President

---

From: Ministerial Services / Services Ministériels (HC/SC) <hc.ministerialservices-servicesministeriels.sc@canada.ca>
Sent: 2020-12-10 2:07 PM
To: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>; Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; McLeod, Robyn (PHAC/ASPC) <robyn.mcleod@canada.ca>; Macey, Jeannette (PHAC/ASPC) <jeannette.macey@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>; Killen, Marita (PHAC/ASPC) <marita.killen@canada.ca>; Ponic, Pamela (PHAC/ASPC) <pamela.ponic@canada.ca>; Currie, Andrea (PHAC/ASPC) <andrea.currie@canada.ca>; Charbonneau, Lise (PHAC/ASPC) <lise.charbonneau@canada.ca>; Chatigny, Elaine (PHAC/ASPC) <elaine.chatigny@canada.ca>; Capes, Jennifer (PHAC/ASPC) <jennifer.capes@canada.ca>; Torunian, Michael (PHAC/ASPC) <michael.torunian@canada.ca>; Wiseman, Vicki (PHAC/ASPC) <vicki.wiseman@canada.ca>
Cc: Hinds, Chris (HC/SC) <chris.hinds@canada.ca>; Maidment, Leanne (HC/SC) <leanne.maidment@canada.ca>; Magee, Heather (HC/SC) <heather.magee@canada.ca>; Allison, Catherine (HC/SC) <catherine.allison@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; HC.F Comms_Coordination F.SC <Comms_Coordination@canada.ca>; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) <phac.OPOCPHO.singlewindow-guichetunique.BPBACSP.aspc@canada.ca>; Russo, Laura (HC/SC) <laura.russo@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>; HC.F CPAB ADMO Advisors F.SC <CPAB_ADMO_Advisors@canada.ca>; Earley, Jaimie (HC/SC) <jaimie.earley@canada.ca>; Richer, Andrea (HC/SC) <andrea.richer@canada.ca>; Gearey, Jennifer (HC/SC) <jennifer.gearey@canada.ca>; Kocent, Marissa (HC/SC) <marissa.kocent@canada.ca>; Payette, Louise (HC/SC) <louise.payette@canada.ca>; HPOC Communications / COPS (PHAC/ASPC)

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<phac.hpoc.communications-cops.aspc@canada.ca>; Eckersley, Jennifer (HC/SC) <jennifer.eckersley@canada.ca>; HC.F Strategic Communications COVID / Communications Stratégiques COVID F.SC <hc.strategiccommunicationscovid-communicationsstrategiquescovid.sc@canada.ca>; Aylward, Brett (HC/SC) <brett.aylward@canada.ca>; Nguyen, Jennifer (HC/SC) <jennifer.nguyen@canada.ca>; Ouellette, Francis (HC/SC) <francis.ouellette@canada.ca>; Aung-Thin, Pamela (HC/SC) <pamela.aung-thin@canada.ca>; Demaine, Erika (HC/SC) <erika.demaine@canada.ca>; Marchand, Katrina (HC/SC) <katrina.marchand@canada.ca>; Roussy, Alyssa (HC/SC) <alyssa.roussy@canada.ca>; Lafkas, Cathy (HC/SC) <cathy.lafkas@canada.ca>; Nahum, Marilyne (HC/SC) <marilyne.nahum@canada.ca>; McLachlan, Kailey (HC/SC) <kailey.mclachlan@canada.ca>

Subject: For RUSH CPHO/Pres approval: NR | Vaccine Injury Support Program (VISP)

Importance: High

Good afternoon,

Please see attached news release for your urgent approval. We understand that the aim is to post the news release at 5 p.m. today.

This is with HPCO ChOps for concurrent approval given the urgency. Edits may follow. This is also with DMO for concurrent approval.

Thank you,

Alyssa

Issue: In early December 2020, the Public Health Agency of Canada began consulting with provinces and territories on establishing a pan-Canadian Vaccine Injury Support Program (VISP). The intention to pursue this program would be announced at the First Minister's Meeting December 10, 2020 (TBC).

NR Approvals:

Simone Gobeil, Mgr (Dec 10)

Stephen Bent, DG (Dec 10)

[redacted]

Megan Bettle, DG, HPFB (Dec 10)

HPOC ChOps (pending)

Heather Magee, Director, CPAB PCRT (FYI)

Cathy Allison, DG, CPAB vaccine communications (FYI)

Dr. Njoo and/or Kim Elmslie (pending)

Pam Aung-Thin, a/ADM, CPAB (Dec 10)

HPFB ADMO (pending)

HPOC EM (pending)

Kaili Levesque, ADMO, COVID-19 Secretariat (FYI)

Cindy Evans, VP (FYI)

DMO (pending)

President/CPHO (pending)

MO (FYI)

PCO (pending)

Alyssa Roussy

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Media Lines –

Vaccine Injury Support Program

Issue: In early December 2020, the Public Health Agency of Canada began consulting with provinces and territories on establishing a pan-Canadian no-fault vaccine injury compensation (VIC) program.

~~The intention to pursue this program would be announced at the Health Minister's Meeting in December, 2020 (TBC). A previously approved holding line is recommended to be used, should media inquire in advance of this announcement~~.

Comms to edit the issue statement to reflect announcement details

~~**Holding line until announced:**~~

~~Vaccination protects individuals from vaccine-preventable diseases. At the same time, it helps protect families, close contacts, communities, and society as a whole. Notwithstanding the rigour of clinical trials and excellence in vaccine delivery, a small number of Canadians will experience an adverse event following immunization, caused by vaccines or their administration. Vaccine injury compensation programs can play an important role in strengthening immunization programs by compensating people who suffer a serious vaccine injury quickly and fairly, without having to incur the additional burden of litigation.~~

~~Quebec is the only jurisdiction in Canada that has a vaccine injury compensation program. Vaccination is a shared responsibility among the federal, provincial and territorial governments, and the federal government is continuing discussions with provinces and territories on this matter.~~

Upon Announcement - Key messages:

- We as Canadians pride ourselves on our commitment to each other. By immunizing, we protect one another and our way of life.
- The Public Health Agency of Canada (PHAC), is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories.
- Building on the model in place in Quebec for over 30 years, ~~T~~this will strengthen national immunization campaigns by ensuring fair and equitable access to support ~~and coverage to vaccines~~ for all individuals immunized in Canada.
- All immunization programs are based on the principle of reciprocity. As such, the Government of Canada ~~We therefore have~~ has a duty to ~~help~~ ensure that Canadians ~~if someone~~ who support public health by being immunized are supported themselves should they happen to experience a rare, ~~fall ill from a~~ serious adverse reaction ~~to a vaccine~~following immunization. This is extremely rare – less than one in a million.
- In the very rare event that a Canadian is faced with uninsured costs resulting from a vaccine that is authorized by Health Canada, they should not spend their time litigating in court for a settlement – they deserve fair compensation.

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- ~~Establishing a VISP program as part of Canada's broader vaccination strategy will help ensure that we remain competitive in accessing new vaccines as they become available, and ultimately protect Canadians.~~
- It also brings Canada in line with its G7 counterparts who ~~that~~ all provide vaccine injury ~~compensation protection~~ support ~~for~~ a minimum of mandatory vaccines, with most covering all recommended vaccines.
- Establishing a VISP as part of Canada's broader vaccination strategy will help ensure that we remain competitive in accessing new vaccines as they become available, and ultimately protect Canadians.
- As the scope of this program is still under discussion with the Provinces and Territories, no further details can be disclosed at this time.

If pressed on state of FPT discussions:
Vaccination is a shared responsibility among the federal, provincial and territorial governments. The federal government regulates vaccines for use in Canada, and the provinces and territories are responsible for the delivery of vaccination programs. The federal government is committed to continued engagement with provincial and territorial governments on the establishment of a pan-Canadian no-fault vaccine injury support ~~program~~ (VISP), noting that Quebec has had a vaccine injury support program since 1988.~~.~~

If pressed on timing:
The establishment of a vaccine injury ~~compensation~~ support program has been previously identified as an area of importance by the Government of Canada, the provinces and the territories, to ensure that Canadians who support public health by being immunized are supported themselves in the rare event they are injured.

If pressed on whether provinces and territories choose to not participate:
Health care is a matter of provincial and territorial jurisdiction. The Public Health Agency of Canada is establishing a pan-Canadian no-fault vaccine injury support program for those provinces and territories who wish to opt-in. Provinces and territories who choose to opt-out will administer their own vaccine injury support program within their jurisdiction. This will provide all Canadians with access to a program.

Questions and Answers:

Q1. Does the Government of Canada have confidence in the COVID-19 vaccines for which it has advance purchase agreements?

Vaccines are a critical way to limit the spread of the virus. They are effective and safe for protecting our health, as well as the health of family and community members.

The safety of Canadians is our first and foremost priority. While vaccines in the past have taken years to come to market, thanks to advances in science and technology, a focused federal response, and an unprecedented level of global cooperation, a COVID-19 vaccine will be available much faster than was previously possible.

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Health Canada received Pfizer's submission on October 9, 2020. The vaccine was authorized under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. The Interim Order allows Health Canada to expedite the review and approval of COVID-19 drugs and vaccines, while maintaining Canada's high standards for safety, efficacy and quality.

Under the Interim Order, Health Canada can accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess information submitted by the manufacturer as it becomes available during the product development process. This new process still involves reviewing all the necessary data thoroughly to support authorization..

The authorization was primarily supported by safety and efficacy data from a randomized, double-blind, placebo-controlled phase 2/3 clinical trial involving about 44,000 participants. Safety was also supported by the results of an earlier trial conducted in Germany and the U.S. that showed participants had an appropriate immune response, and that the vaccine was well tolerated.

Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories, international partners, and the manufacturer. As with all vaccines, Health Canada will take action if any safety issues are identified. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information. The Pfizer-BioNTech vaccine was authorized with terms and conditions that require the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure the benefits of the vaccine continue to be demonstrated through market use.

Q2. What is the likelihood of a possible adverse events following immunization?:

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to assess vaccines for safety and effectiveness in preventing the diseases they target.

Before any vaccine is distributed in Canada, it must receive authorization through Health Canada's rigorous scientific review system. Health Canada will not authorize a vaccine unless evidence demonstrates that its benefits outweigh the risks. Many vaccines are recommended as part of Canadian public health programs to prevent people from getting diseases. These vaccines are given to large numbers of healthy people. This is why regulating the safety, efficacy and quality of vaccines is of particular importance. Adverse events following immunization range from minor reactions (e.g. muscle aches, bruising, mild headache, etc) to very rare but serious adverse events (e.g. paralysis, nerve damage). In addition to the scientific review, there are also reporting systems in place to monitor vaccine safety on an ongoing basis.

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Anyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it to their health care provider. Health care providers are required to report adverse events following immunization to their local public health authority. The public health authority then reports them to the Public Health Agency of Canada.

Once a vaccine is authorized for sale, manufacturers are required to continue submitting information on the safety and effectiveness of the vaccine, to monitor and communicate any potential adverse events following immunization and to take action to mitigate risks. Health Canada will not hesitate to take action if a new or worsening safety issue is identified.

Q2. What about long-term side effects? How can we know Canadians who get the vaccine now won't experience adverse effects years from now?

The Government is committed to protecting the health and safety of Canadians and has a rigorous scientific review system in place to ensure vaccines are safe and effective in preventing the diseases they target.

Canada has a robust and well-established vaccine surveillance system. Once the vaccine is on the market, Health Canada and the Public Health Agency of Canada will monitor for any adverse events after immunization, in collaboration with the provinces and territories and the manufacturer.

Health Canada will continue to review all the available safety data from ongoing clinical studies and will not hesitate to take appropriate action, if required, to protect the health and safety of Canadians. This could include warning Canadians about potential side effects, changing the recommended use of the product, or even removing the product from the market.

To further support Health Canada's efforts to monitor the safety of COVID-19 vaccines, the Interim Order provides the authority to impose terms and conditions on any authorization or establishment licence at any time, such as risk mitigation measures and additional assessments of safety information.

Q3. Are vaccine manufacturers indemnified from legal responsibility for a COVID-19 vaccine?

During a public health emergency such as a pandemic, a large portion of the population will be vaccinated over a short period. Vaccine suppliers have the requirement to produce vaccines quickly and to work with their country's regulator to expedite the regulatory approvals to ensure that the necessary vaccine is available in a timely manner. For these reasons, indemnification of pandemic vaccine suppliers against third-party legal claims is a standard international practice.

Health Canada has the regulatory power to remove vaccines from the market or to impose other conditions on the sale of these drugs to quickly respond to any safety concerns, should they arise. Manufacturers will have to establish and maintain evidence to show the safety of these drugs in order to ensure they can be sold.

At this time, we cannot disclose details of specific agreements in an effort to protect our negotiating position and commercially sensitive pricing information, as well as to respect confidentiality clauses in our vaccine agreements.

Q4. What will a vaccine injury ~~compensation~~ support program look like?

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The Public Health Agency of Canada (PHAC) is establishing a pan-Canadian no-fault vaccine injury support program (VISP), in consultation with the provinces and territories. Establishing a VISP ~~program~~ will strengthen Canada's broader vaccine strategy will help ensure that Canada remains competitive in accessing ~~COVID-19 vaccines and other~~ new vaccines as they become available, and ultimately protect Canadians. It will also align Canada with other G7 countries, all of which have national vaccine injury ~~compensation~~ support programming in place.

As the scope of this program is under discussion with the Provinces and Territories, no further details can be disclosed at this time.

Q5. What will the Government of Canada do to ensure Canadians are confident in the safety of the vaccine that is available to them?

Health Canada will not authorize a vaccine or drug unless evidence demonstrates that its benefits outweigh the risks and that it meets stringent safety, efficacy and quality requirements.

Health Canada is reviewing COVID-19 vaccine candidates under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*. The Interim Order (IO) allows Health Canada to accept rolling submissions for drugs and vaccines that have promising evidence and clinical trials underway. This means that we will accept and assess the information submitted by the manufacturer as it becomes available during the product development process.

This new rolling review process still involves reviewing all the necessary data to support authorization, but it can shorten the time it takes for a new vaccine to be authorized once all the necessary data are available.

COVID-19 vaccine(s) are subject to the same rigorous scientific reviews, quality standards, testing and post-market surveillance as all other vaccines that are approved for use in Canada.

Once a vaccine has been approved for use in Canada, many stakeholders are involved in monitoring its safety and effectiveness (how well it works) in people. At the federal level, Health Canada and the Public Health Agency of Canada share the responsibility for ongoing monitoring, which also involves provincial, territorial and local public health authorities, health care professionals, the vaccine industry and the public.

Q7. What is the Government of Canada doing to address vaccine hesitancy?

The World Health Organization (WHO) identified vaccine hesitancy as one of 10 threats to global health in 2019, threatening to reverse the progress that has been made in addressing vaccine preventable diseases.

Addressing vaccine hesitancy is a priority for the Government of Canada. Efforts to inform and educate Canadians to help build vaccine confidence have been part of PHAC's regular business for years.

For example, from 2017 to 2019, the PHAC conducted a national advertising campaign on childhood vaccination aimed at parents of young children and women who are or expect to become pregnant, to debunk misinformation on vaccine safety and importance. PHAC also

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leads an annual seasonal flu immunization campaign targeting groups, such as seniors over 65 who are especially vulnerable. A subsequent childhood vaccination campaign will launch early in 2021, with similar goals and objectives to the previous one. Similar communications strategies will be used when a new COVID-19 vaccine is released to ensure that Canadians have the proper information to inform their choice to receive the vaccine when available. These campaigns use different approaches to reach different segments of the public, including advertising, public education and outreach. PHAC works with many partners, including provinces and territories and professional associations to implement these strategies.

The Chief Public Health Officer, Dr. Theresa Tam is also working with chief medical officers of health from all provinces and territories through the Special Advisory Committee and together they will work with public health staff across all jurisdictions in Canada to combat misinformation and concerns around the release of a new COVID-19 vaccine.

DRAFT

ATIA - 19(1)

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From: Sharma, Supriya (HC/SC)
Sent: 2021-05-31 3:31 PM
To: CCMOH SECRETARIAT / CMHC (PHAC/ASPC); [redacted] Romano, Anna (PHAC/ASPC); Auger, Julie (PHAC/ASPC); [redacted] Njoo, Howard (PHAC/ASPC); Dr. James Worthington; [redacted] Tam, Dr Theresa (PHAC/ASPC); Wong, Tom (SAC/ISC); Cleary, Eilish (SAC/ISC); Greg Haley; [redacted] Robinson, Kerry (PHAC/ASPC); [redacted] SK CMOH Single Window; [redacted] Vincent Beswick-Escanlar; YK Surveillance;
Cc: [redacted] Barton, Kimby (PHAC/ASPC); Bent, Stephen (PHAC/ASPC); Bettencourt, Sarah (HC/SC); [redacted] Carter, Luke (HC/SC); Mcdougald, Catherine (HC/SC); Charos, Gina (PHAC/ASPC); Cindy Kruger; [redacted] Bedward, Cristina (PHAC/ASPC); [redacted] Davies, Stephanie (PHAC/ASPC); [redacted] Denis, Joel (PHAC/ASPC); [redacted] Elmslie, Kim (PHAC/ASPC); Arnold, Eric (PHAC/ASPC); Evans, Cindy (PHAC/ASPC); Motiwala, Fatema (PHAC/ASPC); [redacted] Guenette, Tara-Lynn (PHAC/ASPC); Hamel, Sonia (PHAC/ASPC); [redacted] Henry, Erin E (PHAC/ASPC); Hostrawser, Bonnie (PHAC/ASPC); HPOC PHM / COPS MSP (PHAC/ASPC); Ingraham, Erin (HC/SC) [redacted] Holubowich, James (PHAC/ASPC); [redacted] Williams, Kathleen (PHAC/ASPC); [redacted] Hunter, Laurie (PHAC/ASPC); Lebans, Anne (PHAC/ASPC); Lewis, Darlene (SAC/ISC); Lior, Lee (PHAC/ASPC); [redacted] MacDonald2, Tammy

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(PHAC/ASPC); MacKenzie, Sara (HC/SC); Caux, Marie-Michele (HC/SC); [redacted] Maureen Carew; [redacted] McCarney, Jane (PHAC/ASPC); McDonald, Alexa (PHAC/ASPC); McGarr, Holly (PHAC/ASPC); McLeod, Robyn (PHAC/ASPC); McNeill, Robin (PHAC/ASPC); Campbell, Meagan (HC/SC); Conly, Meghan (HC/SC) [redacted] Mitra, Debjani (PHAC/ASPC); NB Secretariat ; Paddle, Lisa (PHAC/ASPC); Huber, Pamela (PHAC/ASPC); [redacted] Ponic, Pamela (PHAC/ASPC); [redacted] Romano, Anna (PHAC/ASPC); Russo, Laura (HC/SC); Rutledge-Taylor, Katie (PHAC/ASPC); Salvadori, Marina (PHAC/ASPC); [redacted] Smith, Cheryl (HC/SC); [redacted] Cidsc Secretariat (PHAC/ASPC); Taylor, Dorcas (PHAC/ASPC); [redacted]

Subject: RE: For Response: Seeking SAC feedback on the following PHAC statement, regarding reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines

---

Thanks for sharing – a few comments on the statement:
- agree with other comments to qualify the frequency of the reported events as has been done both with the WHO statement (referred to a small number of cases) and the US CDC statement ("rare, given the number of vaccine doses administered)
- the assessment is ongoing to see if there is indeed a relationship between the AEFIs and the mRNA vaccines. Important to look out for, but not sure it yet qualifies as a "high index of suspicion"
- balance the message a bit more on the side of noting that the Canadian reports have not yet been linked to the vaccine
- may want to also add that there hasn't been any regulatory action on this issue in Canada or internationally to date.

Thanks
Supriya

From: Davies, Stephanie (PHAC/ASPC) **On Behalf Of** CCMOH SECRETARIAT / CMHC (PHAC/ASPC)
Sent: 2021-05-31 1:11 PM
To: [redacted] Romano, Anna (PHAC/ASPC) ; Auger, Julie (PHAC/ASPC) ; [redacted] Adams, Evan (SAC/ISC) ; [redacted] (Ext.) ; Njoo, Howard (PHAC/ASPC) ; Dr. James Worthington ; [redacted] Sharma, Supriya (HC/SC) ; Tam, Dr Theresa (PHAC/ASPC) ; Wong, Tom (SAC/ISC) ; Cleary, Eilish (SAC/ISC) ; Greg Haley [redacted] Robinson, Kerry

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(PHAC/ASPC) ; [redacted] SK CMOH Single Window ; [redacted] Vincent Beswick-Escanlar ; YK Surveillance ; [redacted]

Cc: [redacted] Barton, Kimby (PHAC/ASPC) ; Bent, Stephen (PHAC/ASPC) ; Bettencourt, Sarah (HC/SC) ; [redacted] Carter, Luke (HC/SC) ; Mcdougald, Catherine (HC/SC) ; CCMOH SECRETARIAT / CMHC (PHAC/ASPC) ; Charos, Gina (PHAC/ASPC) ; Cindy Kruger ; [redacted] ; Bedward, Cristina (PHAC/ASPC) ; [redacted] Davies, Stephanie (PHAC/ASPC) ; [redacted] Denis, Joel (PHAC/ASPC) ; [redacted] Elmslie, Kim (PHAC/ASPC) ; Arnold, Eric (PHAC/ASPC) ; Evans, Cindy (PHAC/ASPC) ; Motiwala, Fatema (PHAC/ASPC) ; [redacted] Guenette, Tara-Lynn (PHAC/ASPC) ; Hamel, Sonia (PHAC/ASPC) ; [redacted] Henry, Erin (PHAC/ASPC) ; Hostrawser, Bonnie (PHAC/ASPC) ; HPOC PHM / COPS MSP (PHAC/ASPC) ; Ingraham, Erin (HC/SC) ; [redacted] Holubowich, James (PHAC/ASPC) ; [redacted] Williams, Kathleen (PHAC/ASPC) ; [redacted] Hunter, Laurie (PHAC/ASPC) ; Lebans, Anne (PHAC/ASPC) ; Lewis, Darlene (SAC/ISC) ; Lior, Lee (PHAC/ASPC) ; [redacted] MacDonald2, Tammy (PHAC/ASPC) ; MacKenzie, Sara (HC/SC) ; Caux, Marie-Michele (HC/SC) ; [redacted] Maureen Carew ; [redacted] ; McCarney, Jane (PHAC/ASPC) ; McDonald, Alexa (PHAC/ASPC) ; McGarr, Holly (PHAC/ASPC) ; McLeod, Robyn (PHAC/ASPC) ; McNeill, Robin (PHAC/ASPC) ; Campbell, Meagan (HC/SC) ; Conly, Meghan (HC/SC) ; [redacted] Mitra, Debjani (PHAC/ASPC) ; NB Secretariat ; Paddle, Lisa (PHAC/ASPC) ; Huber, Pamela (PHAC/ASPC) ; [redacted] Ponic, Pamela (PHAC/ASPC) ; [redacted] Romano, Anna (PHAC/ASPC) ; Russo, Laura (HC/SC) ; Rutledge-Taylor, Katie (PHAC/ASPC) ; Salvadori, Marina (PHAC/ASPC) ; [redacted] (Ext.) ; [redacted] Smith, Cheryl (HC/SC) ; [redacted] ; Cidsc Secretariat (PHAC/ASPC) ; Taylor, Dorcas (PHAC/ASPC) ; [redacted]

Subject: For Response: Seeking SAC feedback on the following PHAC statement, regarding reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines

Dear SAC members,

The SAC Secretariat is seeking SAC members feedback on the following PHAC statement, regarding reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines. Please inform the secretariat of any concerns by end of day today, May 31.

The intent of the statement is to

Demonstrate awareness of the international monitoring

To enhance surveillance for myocarditis and pericarditis following COVID-19 vaccination

To inform clinicians to have a high index of suspicion for this condition and to report it

Kind Regards,
SAC Secretariat

****

As described in the May 28 update of the weekly report of Adverse Events Following Immunization (AEFI) with COVID-19 vaccines, the Public Health Agency of Canada (PHAC) and Health Canada are monitoring domestic and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following

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vaccination with COVID-19 mRNA vaccines, including from Israel and the United States. Cases have been reported to occur:

More commonly after the second dose

Typically within several days after vaccination

Mainly in adolescents and young adults, and

More often in males than females.

Most cases appeared to be mild and responded well to conservative treatment and rest, and their symptoms improved quickly. Follow-up on these cases is ongoing.
As part of ongoing COVID-19 vaccine safety efforts, PHAC and Health Canada are closely monitoring myocarditis/pericarditis in passive and active Canadian safety surveillance systems, including the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS), the Canada Vigilance Program (CV) and the Canadian National Vaccine Safety Network (CANVAS). There have been a few reports of pericarditis or myocarditis following COVID-19 mRNA vaccines in Canada. Based on the reports received, we are not currently seeing higher rates than would be expected in the general population as a baseline rate. We are soliciting and monitoring for additional information to assess for any relationship to COVID-19 vaccination.

Myocarditis and pericarditis both involve inflammation of the heart in response to an infection or some other trigger. While myocarditis can be serious, these cases appear to be generally mild and self-limited. Symptoms can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. **Healthcare providers should consider myocarditis and pericarditis in evaluation of acute chest pain or pressure, arrhythmias, shortness of breath or other clinically compatible symptoms after vaccination. They should have a high index of suspicion and consider doing** an electrocardiogram (ECG), troponins, and an echocardiogram**. All cases of myocarditis or pericarditis following vaccination should be reported to the** local health authority**, guided by the recently developed draft case definition for myocarditis from the** Brighton Collaboration**.**

Health Canada, PHAC, and the provincial and territorial health authorities will continue to closely monitor reports of myocarditis and/or pericarditis. Health Canada is also working closely with the manufacturers and international regulators to review information as it becomes available and will take appropriate action as needed. More information will be shared as it becomes available.

The benefits of the mRNA vaccines continue to outweigh their risks in the authorized populations, as there are clear benefits of mRNA vaccines in reducing deaths and hospitalizations due to COVID-19 infections.

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From: Dickson, Samantha M (HC/SC)
Sent: 2020-08-10 10:53 AM
To: Namiesniowski, Tina (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC); Kropp2, Rhonda (PHAC/ASPC)
Subject: RE: [redacted]
Attachments: [redacted]

[redacted]

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From: Dickson, Samantha M (HC/SC)
Sent: 2020-08-10 10:46 AM
To: Namiesniowski, Tina (PHAC/ASPC) ; Tam, Dr Theresa (PHAC/ASPC) ; Kropp2, Rhonda (PHAC/ASPC)
Subject: FW: [redacted]

[redacted]

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An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Recommendations on the use of COVID-19 Vaccines

Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

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PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence-based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

Confidential

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TABLE OF UPDATES

This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, as evidence on these vaccines and COVID-19 evolves, and as recommendations from NACI evolve based on this evidence. This table summarizes the updated information provided in the current version of this document since the publication of the last version of the document on March 16, 2021.

A complete list of changes to this document can be found in the Table of updates: Recommendations on the use of COVID-19 vaccines web page. Complete previous versions of this document are archived and are available through the National Advisory Committee on Immunization (NACI): Statements and publications web page under COVID-19.

Section	Update	Date
Introduction	The goal of Canada's COVID-19 immunization response has been included.	2021-04-20
Epidemiology	A section on variants of concern has been inserted.	2021-04-20
Epidemiology	The section on risk factors has been updated with evidence on factors associated with increased risk of severe outcomes from COVID-19 and increased risk of exposure to COVID-19.	2021-04-20
Efficacy and effectiveness	Emerging evidence on vaccine effectiveness for authorized and available COVID-19 vaccines against severe outcomes and asymptomatic infection has been included.	2021-04-20
Vaccine safety and adverse events following immunization	Information on the recently detected Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) following vaccination with AstraZeneca COVID-19 vaccine has been included.	2021-04-20
Recommendations	NACI's recommendation on the use of COVID-19 vaccines has been updated in light of the safety signal of VITT following vaccination with the AstraZeneca vaccine.	2021-04-20
Recommendations	The summaries of evidence and rationale for the recommendations on populations who were excluded from or included in small numbers in clinical trials of COVID-19 vaccines (immunosuppressed, people with autoimmune conditions, pregnant people, children/adolescents) have been updated to include evidence from a rapid review of risk factors for severe outcomes of COVID-19.	2021-04-20
Recommendations	The summary of evidence and rationale for the pregnancy and breastfeeding recommendations have been updated with additional information from	2021-04-20

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Section	Update	Date
	Developmental and Reproductive Toxicity (DART) animal studies for Pfizer-BioNTech COVID-19 vaccine.	
Management options for COVID-19 vaccines authorized and available for use in Canada	Table 5 has been updated with evidence on protection against variants of concern (VOC), effectiveness against severe outcomes and asymptomatic infection, and recent survey results on vaccine acceptability in Canada. The table has also been updated to include information on VITT following vaccination with AstraZeneca COVID-19 vaccine.	2021-04-20
Appendix B	The vaccine safety and adverse events following immunization section of the Evidence Summary for Moderna COVID-19 vaccine has been updated with information on delayed injection site reactions and facial swelling.	2021-04-20
Appendix C	The vaccine safety and adverse events following immunization section has been updated with information on the recently detected VITT following vaccination with AstraZeneca COVID-19 vaccine.	2021-04-20
Appendix D	Tables capturing the frequency of solicited adverse events following immunization in clinical trials with mRNA and AstraZeneca COVID-19 vaccines have been updated.	2021-04-20
Appendix E	A benefit-risk assessment for the use of AstraZeneca COVID-19 vaccine in a public health context was added.	2021-04-20

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SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT

The following highlights key, current information for immunization providers on COVID-19 vaccines. The evidence on COVID-19 disease and vaccines is evolving. Evidence from clinical trial data is limited due to limitations in the size and duration of follow-up of trial populations. However, clinical trials and studies in the real-world setting are ongoing. NACI will continue to monitor the evidence and update its recommendations as needed. Please refer to the remainder of the Statement for details.

What

Disease

- Novel coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.
- Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors that may intersect. Risk factors for exposure and severe disease may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations.

Currently authorized and available vaccines
(Pfizer BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine)

- mRNA vaccines are authorized for use in Canada for individuals 16 years of age and older (Pfizer-BioNTech COVID-19 vaccine) or 18 years of age and older (Moderna COVID-19 vaccine).
- A non-replicating viral vector vaccine is authorized for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine).
- In clinical trials, all COVID-19 vaccines are efficacious in the short-term against symptomatic, confirmed COVID-19 disease; trials are ongoing. mRNA COVID-19 vaccines have demonstrated high efficacy (approximately 94%). The AstraZeneca COVID-19 vaccine has demonstrated an average efficacy of approximately 62% in those 18-64 years of age. In adults 65 years of age and older who received one dose of AstraZeneca, real-world observational data of vaccine effectiveness have shown a reduction in the risk of symptomatic disease and hospitalization.
- There is currently limited evidence on the duration of protection and on the efficacy of these vaccines in reducing transmission of SARS-CoV-2, although studies are ongoing. Evidence of protection against asymptomatic SARS-CoV-2 infection is emerging for the mRNA vaccines.
- Evidence of varying protection offered by COVID-19 vaccines against SARS-CoV-2 variants is evolving. To date, evidence has emerged that the Pfizer-BioNTech and AstraZeneca vaccines offer protection against the B.1.1.7 variant of concern first identified

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in the UK. For all vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. In clinical trials of mRNA vaccines, some adverse events, including fever, are more frequent after the second dose; this was not the case with the AstraZeneca COVID-19 vaccine.

- Following post-licensure use of AstraZeneca COVID-19 vaccine, rare cases of serious blood clots associated with thrombocytopenia have recently been reported in Europe (with two confirmed cases out of over 700,000 doses of AstraZeneca COVID-19 vaccine administered in Canada as of April 17, 2021) mostly between 4 and 14 days after receipt of the vaccine. The rate of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) has been estimated to be between 1 per 26,000 and 1 per 500,000 vaccinated with the AstraZeneca COVID-19 vaccine. Investigations are ongoing.
- There is currently minimal evidence to inform on differences in vaccine efficacy, effectiveness, or safety between individuals with and those without prior evidence of SARS-CoV-2 infection at the time of vaccination.

Who

NACI makes the following recommendations:

A complete series with an mRNA COVID-19 vaccine *should be* preferentially offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered.

A complete series with the AstraZeneca COVID-19 vaccine *may be* offered to individuals without contraindications in select age ranges* in areas where COVID-19 activity is high or very high ONLY if the individual does not wish to wait for an mRNA vaccine AND ALL of the following conditions apply:

a) The benefit-risk analysis** determines that the benefit of earlier vaccination with the AstraZeneca COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
b) As part of benefit-risk analysis, the following is considered (in addition to other factors)**: The risk of severe outcomes of COVID-19 decreases with decreasing age. In age groups younger than 50 years of age, the benefit provided by offering AstraZeneca COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty; AND
c) The benefits and relative risk** and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND
d) There will be substantial delay to receive an mRNA vaccine.

Note: AstraZeneca COVID-19 vaccine should not be offered in areas of very low, low, or moderate COVID-19 activity.

***Decision tool to help identify in which age ranges the AstraZeneca COVID-19 vaccine may be considered (in the context of other factors considered in the Risk Assessment Framework**)**

Local COVID-19 activity	Age range where the benefit of AstraZeneca COVID-19 vaccine may outweigh the risk
High (≥3 COVID-19 cases/ 10,000 per day)	50 years and older

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Very High (≥6 COVID-19 cases/10,000 per day)	40 years and older

Please see Appendix E for details, limitations, and uncertainties

**See Risk Assessment Framework and Management Options Table to assist with this determination

A complete vaccine series with a currently authorized COVID-19 vaccine *may be* offered to:

- Individuals in the authorized age group without contraindications to the vaccine who have had previously polymerase chain reaction (PCR)-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.

For some specific populations who were either excluded from, or were represented by small numbers of participants in clinical trials, NACI recommends that a complete vaccine series with a currently authorized COVID-19 vaccine may be offered, if a risk assessment deems that the benefits of vaccination outweigh the potential risks for the individual (e.g., where the risk of severe outcomes of COVID-19 and/or risk of exposure to SARS-CoV-2 is high) or for the fetus/infant (in the case of pregnancy/breastfeeding) and if informed consent includes discussion about the insufficient evidence in these populations:

- Immunosuppressed due to disease or treatment
- Individuals with an autoimmune condition
- Pregnant or breastfeeding
- Adolescents 12 to 15 years of age (Only Pfizer-BioNTech COVID-19 vaccine may be offered)

These recommendations may change as more evidence on safety and/or efficacy/effectiveness in these populations becomes available.

NACI also recommends that:

- All individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time, due to insufficient evidence on the duration of protection and effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.

- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.

- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded or remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's

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guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.

- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, seniors living in congregate care settings, children and adolescents) is recommended.

NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization:

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.

- Jurisdictions should ensure close and rapid monitoring of safety, coverage and effectiveness of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.

- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

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How

- Currently authorized and available COVID-19 vaccines are administered intramuscularly in a two-dose schedule (Pfizer-BioNTech, Moderna, AstraZeneca).
- Attempts should be made to complete the vaccine series with the same vaccine product.
- Serologic testing is not needed before or after receipt of a COVID-19 vaccine to assess susceptibility to SARS-CoV-2 or immune response to the vaccine.
- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines at this time, unless other vaccines are required for post-exposure prophylaxis.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

Why

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption in Canada and worldwide.
- The authorized, available COVID-19 vaccines that are recommended for use by NACI in this Statement have been shown to be safe (with the exception of very rare cases of VITT reported following vaccination with the AstraZeneca vaccine), efficacious against symptomatic laboratory confirmed COVID-19, and appear to protect against severe disease, hospitalization and death due to COVID-19.

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I. INTRODUCTION

The overall goal of Canada's pandemic response is to minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic. The goal of Canada's COVID-19 immunization response is: To enable as many Canadians as possible to be immunized against COVID-19 as quickly as possible, while ensuring that high risk populations are prioritized.

This guidance document will provide recommendations on the use of authorized COVID-19 vaccines as they are approved and available for use in Canada, and as evidence on these vaccines evolves.

There are four COVID-19 vaccines currently authorized for use in Canada, but only three (Pfizer-BioNTech, Moderna, AstraZeneca) are currently available:

1. The Pfizer-BioNTech COVID-19 vaccine was authorized for use in Canada on December 9, 2020.
2. The Moderna COVID-19 vaccine was authorized for use in Canada on December 23, 2020.
3. The AstraZeneca COVID-19 vaccine was authorized for use in Canada on February 26, 2021.
    - Health Canada authorized two manufacturers to produce this vaccine developed by AstraZeneca and Oxford University: AstraZeneca and Serum Institute of India (SII). NACI has not specifically reviewed evidence for the SII vaccine, but Health Canada has deemed SII and AstraZeneca vaccines to be comparable. Authorization of the SII COVID-19 vaccine (COVISHIELD) was based on its comparability to the AstraZeneca COVID-19 vaccine as determined by evaluation and direct comparison of manufacturing processes and controls and the quality characteristics of the two products. The results of this comparison by Health Canada determined that the two products were sufficiently similar and that the efficacy, immunogenicity and safety of COVISHIELD could be inferred from the non-clinical and clinical studies from the AstraZeneca COVID-19 vaccine.
4. The Janssen COVID-19 vaccine was authorized for use in Canada on March 5, 2021.

The evidence on COVID-19 and COVID-19 vaccines has been rapidly evolving. To date, NACI has published the following evidence-informed guidance:

1. Research priorities for COVID-19 vaccines to support public health decisions to inform clinical trials of candidate COVID-19 vaccines to protect against infection, serious illness, and deaths caused by SARS-CoV-2.
2. Preliminary guidance on key populations for early COVID-19 immunization to plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.
3. Guidance on the prioritization of initial doses of COVID-19 vaccine(s) for the efficient and equitable prioritization of initial doses of COVID-19 vaccines to assist with the planning for allocation of the first COVID-19 immunization programs.
4. Guidance on the prioritization of key populations for COVID-19 immunization to provide guidance for the equitable, ethical, and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others.

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5. Rapid response: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada to maximize the number of individuals benefiting from the first dose of vaccine by extending the interval for the second dose up to four months after the first. This was followed by a more comprehensive NACI statement providing a detailed overview of the evidence and considerations leading to NACI's recommendation.
6. Rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults (AstraZeneca vaccine should not be used in adults under 55 years of age at this time) while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) [now and hereafter referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)] following vaccination with AstraZeneca COVID-19 vaccine is investigated further.
7. Recommendations on the use of COVID-19 vaccine initially published on December 12, 2020 and updated iteratively as new evidence becomes available and with the authorization of additional COVID-19 vaccines. This statement reflects the most up to date guidance.

Guidance Objective

The objective of this advisory committee statement is to provide evidence-informed guidance on the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada. This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, and as the evolution of evidence on these vaccines or the pandemic situation warrants changes in guidance. In this guidance document, the evidence and rationale for recommendations as well as current knowledge gaps will be summarized. Evidence summaries on vaccine characteristics for specific COVID-19 vaccines will be included in appendices.

II. METHODS

Details of NACI's recommendation development process can be found elsewhere [1, 2].

In brief, the broad stages in the preparation of this NACI advisory committee statement included:

1. Knowledge synthesis
2. Synthesis of the body of evidence of benefits and harms, considering the quality of the synthesized evidence and magnitude and certainty of effects observed across the studies
3. Translation of evidence into recommendations.

In order to develop comprehensive, appropriate immunization program recommendations, NACI considers a number of factors. In addition to critically appraising evidence on burden of disease and vaccine characteristics such as safety, efficacy, immunogenicity and effectiveness, NACI uses a published, peer-reviewed framework and evidence-informed tools to ensure that issues related to ethics, equity, feasibility, and acceptability (EEFA) are systematically assessed and integrated into its guidance [2]. The NACI Secretariat applied this framework with accompanying evidence-informed tools (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, Acceptability Matrix) to systematically consider these programmatic factors for the development of clear, comprehensive, appropriate recommendations for timely, transparent decision-making. For details on the development and application of NACI's EEFA Framework and evidence-informed

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tools (including the Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, and Acceptability Matrix), please see https://doi.org/10.1016/j.vaccine.2020.05.051.

For this advisory committee statement, NACI used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to develop population-focused recommendations. Further information on this framework can be found in the GRADE handbook, available at: https://training.cochrane.org/resource/grade-handbook

NACI reviewed and approved the key policy questions used to guide recommendation development on November 25, 2020 and rated the outcomes for their importance for decision-making. With evolving evidence, NACI rated outcomes again on March 21, 2021. The Canadian Immunization Committee (CIC) provided feedback on the key policy questions to ensure alignment with program needs. Important ethical considerations relating to the key policy questions were presented on November 26, 2020, December 15, 2020, January 26, 2021 and April 6, 2021 to the PHAC Public Health Ethics Consultative Group, who provided an assessment of ethical considerations that are relevant to the development of recommendations. Knowledge synthesis and quality appraisal were performed by the NACI Secretariat for unpublished clinical trial evidence and were informed by NACI's rating of the outcomes. Unpublished data from Phase 1, 2, and 3 clinical trials were presented to the High Consequence Infectious Disease Working Group and NACI for discussion. Proposed recommendations were then presented and approved at emergency NACI meetings. The description of relevant considerations, rationale for specific decisions, and knowledge gaps are described in the text.

Key Dates

- Pfizer-BioNTech COVID-19 vaccine was discussed on December 4, 2020 and related recommendations were approved on December 7, 2020.
- The Moderna COVID-19 vaccine was discussed on December 14, 2020 and related recommendations were approved on December 17, 2020.
- The AstraZeneca COVID-19 vaccine was discussed on January 19, 28, February 5, and February 24, 2021 and related recommendations were approved on February 24, 2021.
- Considerations regarding an extended interval between authorized vaccine doses in the context of limited vaccine supplies, and clarifications to recommendations for populations who were either excluded from or were represented by small numbers of participants in clinical trials were discussed on January 7, 2021 and were approved on January 8, 2021.
- Additional evidence on an extended interval of 4 months between authorized vaccine doses in the context of limited vaccine supplies was reviewed on February 8, 19, and 24-25, 2021. Related recommendations were approved on March 1, 2021. Between March 25 and March 28, 2021, NACI members revisited these recommendations as they relate to specific population groups.
- Additional evidence from observational studies of effectiveness of the AstraZeneca vaccine in those 65 years of age and over was reviewed on March 10, 2021. Related recommendations were approved on March 13, 2021.
- Evolving evidence of VITT following the use of AstraZeneca COVID-19 vaccine was formally reviewed on April 13 and 15, 2021. Related recommendations were approved on April 17, 2021.

III. EPIDEMIOLOGY

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Information on COVID-19 is continually evolving. The following section will describe the current basis of knowledge, with an emphasis on the best available Canadian data where possible. To access the most recent updates to specific elements, please refer to the links below.

Disease description

Infectious agent

COVID-19 is caused by the SARS-CoV-2, which was first recognized in Wuhan, China in December 2019.

Transmission

Current evidence suggests that SARS-CoV-2 is spread through respiratory droplets and aerosols created when an infected person coughs, sneezes, sings, shouts, or talks. A person may be infectious for up to three days before showing symptoms.

More information on the transmission of SARS-CoV-2 can be found on the PHAC webpages for COVID-19: Main modes of transmission and COVID-19 signs, symptoms and severity of disease: A clinician guide

Variants of concern

Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.

More information on the variants of concern (VOC) reported in Canada is available in the COVID-19 epidemiology update. The COVID-19 Weekly Epidemiological Update by the World Health Organization provides a summary on the global distribution and emerging evidence on VOC and variants of interest.

NACI will continue to monitor the epidemiology and evidence pertaining to VOC and COVID-19 vaccines.

Risk factors

Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or occupational settings), and some populations are at increased risk of severe disease and outcomes (e.g., hospitalization and death) due to various biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., socioeconomic status, belonging to a racialized population) factors that may intersect. Exposure and risk of severe disease factors may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations characterized by increased rates of infection and disease, severe illness, hospitalizations, and/or deaths.

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Please see NACI's Advisory Committee Statement on Key Populations for Early COVID-19 Immunization and the Equity Matrix [3] for a summary of inequities associated with COVID-19, potential reasons for and intersections between these inequities, and suggested interventions to reduce inequities and improve access to vaccines. NACI's Guidance on the prioritization of key populations for COVID-19 immunization builds on the foundational framework for the equitable, ethical and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others. This guidance was informed by evolving evidence on risk factors for COVID-19.

Table 1 summarizes populations at risk of severe outcomes from COVID-19 (hospitalization and/or mortality) based on the results of an updated rapid review of evidence from studies in Organisation for Economic Co-operation and Development (OECD) countries, as well as populations at increased risk of exposure to COVID-19 (due to inability to physically distance and/or reduced access to infection prevention and control measures) identified, in part, through Canadian reports (epidemiological or analytic).

The review by the Alberta Research Centre for Health Evidence (ARCHE) found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with age 60-69 years versus <60 years. A previous review by ARCHE found a moderate certainty of evidence for at least a 5-fold increase in mortality and hospitalization with age over 70 years (versus 45 years and younger). Studies treating age on a continuum or across small increments consistently found that risks for hospitalization and mortality increased with increasing age (e.g., approximately 2-6% and 5-10% relative increase in risk per year) [4].

The ARCHE review found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with a small number of medical conditions (classified as Level 1 in Table 1). The review found a low certainty of evidence for at least a 2-fold increase in mortality from COVID-19, and/or a low or moderate certainty of evidence for at least a 2-fold increase in hospitalization for a longer list of medical conditions (classified as Level 2 in Table 1). A moderate certainty of evidence of at least a 2-fold increase in hospitalization and mortality from COVID-19 in people living with two or more medical conditions was found. However, there is no direct evidence on the combination of medical conditions that increase this risk [4].

Caution should be taken when interpreting evidence of low certainty (e.g., for medical conditions listed as Level 2 in Table 1). As evidence accumulates, observed associations may change. For example, a previous rapid review by ARCHE [4] found low certainty evidence for at least a 2-fold increase in hospitalization or mortality for males, people with liver disease, and people with heart failure. As evidence has accumulated, there is now stronger evidence for little-to-no increased association of severe outcomes in these populations. The list of medical conditions included in Table 1 may not be comprehensive as it is based only on evidence from published studies included in the ARCHE review.

Table 1. Summary of risk factors for severe outcomes from COVID-19 and increased risk of exposure to COVID-19

Increased risk of severe outcomes from COVID-19 (hospitalization/mortality)[a]	Increased risk of exposure to COVID-19 [5] (e.g., due to inability to physically distance/reduced access to IPC)[b]
Increasing age (strong evidence) (based on moderate certainty of evidence of ≥2-fold increase in mortality)	• Residents and staff of congregate living settings that provide care for

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• ≥60 years (particularly ≥ 70 years) [5]	seniors • Frontline healthcare workers
Medical conditions – Level 1 (strong evidence) [5] (based on moderate or high certainty evidence of ≥2-fold increase in mortality) • Down syndrome • End-stage kidney disease • Epilepsy • Motor neuron disease, multiple sclerosis, myasthenia gravis, Huntington's disease[5] • Type 1 and 2 diabetes	• Adults in Indigenous communities • Residents and staff of other congregate living settings (e.g., quarters for migrant workers, shelters, correctional facilities, group homes)
Medical conditions – Level 2 (limited evidence) [5] **Level 2a** (based on low certainty of evidence of ≥2-fold increase in mortality • Cerebral palsy • Major psychiatric disorder (schizophrenia, schizoaffective disorder, or bipolar disorder); in combination with drug use for the condition in the past 6 months • Obesity class III (BMI 40 kg/m2 or more) • Parkinson's disease • Sickle cell disease or severe immunodeficiency, transplant (any type) • Kidney transplant, • Recent bone marrow or stem cell transplant • Metastatic cancer • Recent/current chemotherapy or radiotherapy **Level 2b** (based on low or moderate certainty of evidence of ≥2-fold increase in hospitalization) • Previous cerebrovascular accident • Pregnancy (any stage) • Frailty (among community and non-community dwelling people; measured on scales that include items such as weight loss, exhaustion, physical activity, walking speed, grip strength, overall health, disability, presence of disease, dementia, falls, mental wellbeing)	• Adults in racialized and marginalized communities • First responders (e.g., police, firefighters) • Frontline essential workers who cannot work virtually
Increased risk of severe outcomes (hospitalization/mortality)[c] and Increased risk of exposure [5]	
• Long-term care residents • Visible minority groups (includes mainly South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean, Japanese)	

[a] Identified through rapid review of evidence from OECD countries for an independent association with severe outcomes from COVID

[b] Identified, in part, through Canadian epidemiological reports

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[e] Identified through rapid review of Canadian studies that may have an association with hospitalization and mortality from COVID-19. These studies may not have accounted for other covariates.

[§] These conditions were grouped within a single study; evidence for the individual conditions is either unavailable or of lower certainty.

The list of medical conditions in Table 1 may differ from those in other jurisdictions due to differences in local epidemiology and differing levels of evidence considered. Many jurisdictions include medical conditions involving the heart, lungs, liver and spleen. The ARCHE review found fairly strong evidence (moderate certainty) of little-to-no increase in severe outcomes for several cardiovascular and respiratory conditions. There was some evidence (low certainty) for little-to-no increase in hospitalization or mortality with cirrhosis. No studies met selection criteria for other liver conditions, asplenia, or splenic dysfunction.

The evidence on risk factors for COVID-19 continues to evolve.

Spectrum of clinical illness

The median incubation period for non-variant SARS-CoV-2 has been estimated to be 5 to 6 days from exposure to symptom onset, with most individuals (97.5%) developing symptoms within 11.5 days of exposure. The incubation period ranges from 1 to 14 days.

Clinical presentation and symptoms of COVID-19 vary in frequency and severity. To date, there is no list of symptoms that has been validated to have high specificity or sensitivity for COVID-19.

More information on the spectrum of clinical illness is available on the PHAC webpage for COVID-19 signs, symptoms and severity of disease: A clinician guide.

Disease incidence

Global
Updated international data on COVID-19 cases and deaths is available at:
https://health-infobase.canada.ca/covid-19/international/

Weekly epidemiological updates highlighting key global, regional and country-level data on COVID-19 cases and deaths are available from the World Health Organization (WHO) at:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

National
Updated national, provincial and territorial-level data on COVID-19 cases and deaths in Canada over time is available from the PHAC webpage on Coronavirus disease (COVID-19): Outbreak update.

IV. VACCINES

The following section summarizes information about COVID-19 vaccines authorized and available for use in Canada. More detailed vaccine-specific information is included in Appendices A through D. The current landscape of all candidate COVID-19 vaccines in clinical evaluation can be found on the WHO webpage Draft landscape of COVID-19 candidate vaccines. Under the Interim Order

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Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, Health Canada can make regulatory decisions for COVID-19 vaccines that have completed Phase 3 clinical trials for authorized use in Canada.

Most vaccine candidates in development that may become authorized for use in Canada use various technologies to deliver SARS-CoV-2 spike protein to vaccine recipients. This protein is expressed on the surface of the SARS-CoV-2 virus and is a major target for binding and neutralizing antibodies as well as cell-mediated immune responses.

mRNA vaccines

COVID-19 vaccines that use messenger RNA (mRNA) platforms contain modified nucleotides that code for the SARS-CoV-2 spike protein. A lipid nanoparticle formulation delivers the mRNA into the recipient's cells. Once inside the cytoplasm of a cell, the mRNA provides instructions to the cell's protein production machinery to produce the trans-membrane spike protein antigen that becomes anchored on the cell's external surface. The mRNA does not enter the nucleus of the cell and does not interact with, or alter, human DNA. The immune system is engaged by both the transmembrane spike protein and immune receptors carrying spike antigens to induce humoral and cellular immune responses. The mRNA, lipid nanoparticle, and spike protein are degraded or excreted within days to weeks from time of immunization. mRNA vaccines are not live vaccines and cannot cause infection in the host.

Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

Non-replicating viral vector vaccines

COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells. The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease (i.e., they are non-replicating). Once inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell. The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd).

IV.1 Preparations of COVID-19 vaccines authorized and available for use in Canada

Table 2. COVID-19 vaccines available for use in Canada

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 / Covishield Vaccine
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)
Date of authorization in Canada	December 9, 2020	December 23, 2020	February 26, 2021
Authorized ages for use	16 years of age and older	18 years of age and older	18 years of age and older
Dose	0.3 mL (30 mcg of mRNA)[a]	0.5 mL (100 mcg of mRNA)	0.5 mL (5×10^{10} viral particles)
Authorized Schedule [b]	2 Doses, 3 weeks apart	2 Doses, 4 weeks apart	2 Doses, 4 to 12 weeks apart
Route of administration	IM	IM	IM

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Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 / Covishield Vaccine
Nature of the antigen	Transmembrane prefusion spike protein	Transmembrane prefusion spike protein	Transmembrane spike protein
Adjuvant (if present)	None	None	None
Primary storage requirements pre-puncture[c]	-80°C to -60°C	-25°C to -15°C[d]	+2°C to +8°C
Additional storage options pre-puncture[c]	-25°C to -15°C for up to 2 weeks[e] OR 120 hours (5 days) at +2°C to +8°C AND/OR 2 hours up to +25°C	30 days at +2°C to +8°C AND/OR 12 hours at +8°C to +25°C	+2°C to +8°C
Diluent	Yes	No	No
Usage limit post-puncture	6 hours at +2°C to +25°C[f]	6 hours at +2°C to +25°C	6 hours at room temperature (up to +30°C) **or** 48 hours at +2°C to +8°C.
Formats available	Multi-dose vial (6 doses)[a], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (8-and 10-dose presentations), preservative-free

Abbreviations: ChAd: Chimpanzee adenovirus; IM: Intramuscular; mRNA: Messenger ribonucleic acid

[a] After dilution, one vial contains 6 doses of 0.3 mL each. However, vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in the product monograph supersedes the number of doses stated on vial labels and cartons. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.Refer to the product monograph available through Health Canada's Drug Product Database for choice of diluent, dilution instructions and type of syringes which can be used to extract 6 doses from a single vial.

[b] Authorized schedule per the product monograph. For NACI recommendations on intervals between doses, refer to Table 3.

[c] Protected from light during storage

[d] Do not store on dry ice or below -40°C

[e] Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

[f] After dilution, vaccine must be used within 6 hours

IV.2 Efficacy and Effectiveness

Due to the availability of only short-term clinical trial data, the duration of protection provided by COVID-19 vaccination is currently unknown. However, studies are ongoing.

The following section highlights key efficacy and effectiveness data for authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and the authorized, available viral vector-based COVID-19 vaccine (AstraZeneca COVID-19 vaccine) only. For additional details regarding trial design, including study population, length of follow-up, and efficacy for the authorized and available vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine) and Appendix C (for the AstraZeneca COVID-19 vaccine).

Efficacy against symptomatic COVID-19 disease

The currently authorized mRNA COVID-19 vaccines have been shown to be highly efficacious in the short term against confirmed symptomatic COVID-19 disease (presence of one or more symptoms plus laboratory confirmation of SARS-CoV-2 infection) from one to two weeks after receiving the full two-dose series. The authorized mRNA vaccines are similarly efficacious in adults with one or more comorbidities, as well as in younger adults and older adults. However,

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evidence in adults of a much more advanced age (e.g., 85 years and older) and in long-term care facilities is limited.

In clinical trials, AstraZeneca COVID-19 viral vector vaccine has shown moderate short-term efficacy against symptomatic COVID-19 disease (presence of at least one pre-defined COVID-19 symptom plus laboratory confirmation of SARS-CoV-2 infection) in adults 18–64 years of age, at least two weeks after receiving the full series of two standard doses of the vaccine. Clinical trial data show that efficacy increased as the interval between doses increased. At present, there are insufficient clinical trial data in adults ≥65 years of age to assess vaccine efficacy in this age group. The vaccine is similarly efficacious in adults ≥18 years of age with and without pre-defined comorbidities (presence of one or more mild to moderate and controlled cardiovascular disease, respiratory disease, diabetes or obesity).In the initial absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized in Appendix C. These studies provide effectiveness estimates following the first dose of AstraZeneca vaccine and have shown a reduction in the risk of symptomatic disease and hospitalization that appears to reach a comparable level to that observed among persons of similar age who received one dose of mRNA vaccine.

The clinical trial data demonstrates that the authorized mRNA COVID-19 vaccines are efficacious over the short-term in individuals with or without evidence of prior SARS-CoV-2 infection. However, participants with laboratory-confirmed SARS-CoV-2 infection prior to enrollment were excluded from the trials and the number of trial participants with evidence of previous infection (as defined by trial protocol) who had confirmed symptomatic COVID-19 disease during the trials were small; therefore, the efficacy in this population and how it compares to those without evidence of previous infection is unknown at this time.

The first dose of the authorized COVID-19 vaccines has been shown to offer at least short-term protection against confirmed COVID-19 disease. For mRNA vaccines, the highest efficacy is seen after the second dose is administered. There is currently no available evidence on medium- and long-term efficacy of the authorized COVID-19 vaccines, however trials are ongoing and this Statement will be updated as evidence emerges.

Efficacy and effectiveness against severe disease

The clinical trials of the authorized and available COVID-19 vaccines assessed efficacy against severe COVID-19 disease, but not all provided sufficient data to be able to assess the efficacy against hospitalizations or deaths.

The authorized mRNA COVID-19 vaccines appear efficacious against severe COVID-19 outcomes based on clinical trial data used for authorization (severe outcomes were defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death). However, the number of severe cases that have been observed to date was small in the Pfizer-BioNTech clinical trial and was too small in the AstraZeneca clinic trial to assess efficacy. Efficacy against hospitalization was not assessed in the clinical trials of the mRNA vaccines, but evidence from the clinical trials involving the AstraZeneca vaccine is suggestive of a protective effect against hospitalization. To date there have been very few COVID-19 associated deaths identified in the clinical trials making it difficult to assess efficacy against this outcome. However, of the

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COVID-19 associated deaths identified in clinical trials, none have been in study participants receiving COVID-19 vaccines.

Emerging real world evidence from studies in the United Kingdom (UK) [6-8], Israel [9-11], the United States (US) [12], and Canada [13] suggests moderate to high vaccine effectiveness against severe COVID-19 outcomes after the first or second dose of mRNA COVID-19 vaccines,[6-13], and after the first dose of AstraZeneca COVID-19 vaccine, [6-8], including in older [6-8, 11] and frail [6] populations. COVID-19 related hospitalization was the most common severe COVID-19 outcome assessed, [6-9, 12], while fewer studies provided estimates of effectiveness against severe disease [9, 10] and death [7, 9, 13]. Emerging evidence from two Israeli studies suggest high vaccine effectiveness after the second dose of Pfizer-BioNTech COVID-19 vaccine against severe disease [9, 10] and COVID-19 related hospitalization [9]. Studies for COVID-19 vaccines are ongoing and new effectiveness data against severe COVID-19 outcomes will be assessed as it emerges.

Efficacy and effectiveness against asymptomatic infection and transmission
Preliminary data from the ongoing Moderna COVID-19 vaccine trial showed a lower prevalence of SARS-CoV-2 positivity by PCR in asymptomatic participants at one particular time point (after Dose one but before Dose 2), and therefore viral shedding, in the group that received the vaccine compared to the placebo group. However, the current data are insufficient to draw conclusions. Exploratory analyses for the AstraZeneca viral vector vaccine has not demonstrated efficacy against confirmed SARS-CoV-2 asymptomatic infection, however the number of asymptomatic infections was small. Studies are ongoing for these vaccines.

Evidence has begun to emerge from post-marketing studies conducted in Israel, [9] the UK, [14] and the US [15] on the effectiveness of COVID-19 vaccines against asymptomatic infection. Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose [9, 14] (depending on time since vaccination) and high after the second dose [9, 14]. Similar results were reported for mRNA COVID-19 vaccines in general (i.e., Moderna and Pfizer-BioNTech) [15]. In one UK study, asymptomatic SARS-CoV-2 infections were significantly less likely to be identified in vaccinated participants compared to those who were unvaccinated [14]. There are no results specific to other COVID-19 vaccines yet, but studies are ongoing.

Efficacy and effectiveness against variants
Evidence of varying protection and effectiveness offered by authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and the currently available viral vector-based COVID-19 vaccine (AstraZeneca COVID-19 vaccine) against variants of SARS-CoV-2 is evolving. Please see Table 5 for a summary of this evidence.

There is evidence that both the Pfizer and AstraZeneca vaccines protect against the B.1.1.7 SARS-CoV-2 variant first identified in the UK. The AstraZeneca clinical trial was conducted when the B.1.351 lineage was the predominant strain in South Africa, and vaccine efficacy was not demonstrated against this strain.

NACI will continue to monitor the evidence and update recommendations as needed.

IV.3 Immunogenicity

No immunological correlate of protection has been determined for SARS-CoV-2; therefore, all immunological evidence in support of vaccine efficacy is indirect and cannot directly be used to estimate either vaccine efficacy or effectiveness.

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There are several key knowledge gaps that affect the understanding of immune responses to COVID-19 vaccine:

- Which type of immune responses are important for protection from infection, severe disease, or transmission
- The durability of immune responses and how they may change over time
- How immune responses to natural infection compare to responses elicited from a vaccine
- How immune responses differ across populations (e.g., in immunocompromised, children) or by SARS-CoV-2 serostatus (i.e., past COVID-19 infection)
- How immune responses differ based on previous infection with non-SARS-CoV-2 coronaviruses

Due to limitations in the number of participants and duration of follow up from COVID-19 clinical trial data, long-term evidence on immunogenicity is unknown. However, studies are ongoing.

The following section highlights key immunogenicity data for the authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine) and viral vector based COVID-19 vaccine (AstraZeneca COVID-19 vaccine) only. For additional details regarding trial design, including study population and length of follow-up, and immunogenicity for these authorized vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine) and Appendix C (for the AstraZeneca COVID-19 vaccine).

Humoral immune responses

All authorized COVID-19 vaccines induce humoral immune responses, including binding and neutralizing antibody responses. Humoral responses peaked after the second dose of mRNA vaccine, and after the second dose of AstraZeneca COVID-19 vaccine in participants who were not previously infected. Some vaccines induce higher immune responses in younger populations.

Viral vector-based vaccines may induce anti-vector immune responses, which may impact future vaccine efficacy and effectiveness and may vary by age, dose, and interval between doses.

Cellular immune responses

All authorized, available COVID-19 vaccines have been shown to produce cellular immune responses. Cellular immune responses increased after the second dose of mRNA COVID-19 vaccine, while responses for AstraZeneca COVID-19 vaccine were maintained or decreased after the second dose.

IV.4 Vaccine Administration

For additional vaccine product-specific information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Vaccine Administration Practices in the Canadian Immunization Guide (CIG), Part 1 - Key Immunization Information for additional general information.

As for the routine administration of all vaccines, COVID-19 vaccines should be administered in settings capable of managing anaphylaxis. Refer to Anaphylaxis and other Acute Reactions Following Vaccination in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

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IV.4.1 Dose, route of administration, and schedule

Dose

Pfizer-BioNTech COVID-19 Vaccine

Each dose is 0.3 mL after dilution, containing 30 mcg of SARS-CoV-2 spike protein mRNA.

The dose for the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

Moderna COVID-19 Vaccine

Each dose is 0.5 mL, containing 100 mcg of SARS-CoV-2 spike protein mRNA.

No dilution is required.

AstraZeneca COVID-19 Vaccine

Each dose is 0.5 mL, containing 5×10^{10} particles of SARS-CoV-2 spike protein.

No dilution is required.

Route of administration

COVID-19 vaccines are given as an intramuscular (IM) injection into the deltoid muscle.

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional general information.

Schedule

Refer to Table 3 for a summary of immunization schedules for authorized, available COVID-19 vaccines.

Table 3. Recommended immunization schedule, by COVID-19 vaccine

Vaccine product	Immunization schedule	Minimum interval	Authorized interval	Extended interval[a]
Pfizer-BioNTech COVID-19 vaccine	2-dose schedule	19 days[b]	21 days	16 weeks
Moderna COVID-19 vaccine	2-dose schedule	21 days[c]	28 days	16 weeks
AstraZeneca COVID-19 vaccine	2-dose schedule	28 days	4 to 12 weeks	16 weeks[d]

[a] Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing

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pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine up to four months after the first. NACI will continue to monitor the evidence and update this interval as needed.

[b] The basis for this minimum interval is that the per-protocol design for the Pfizer-BioNTech COVID-19 vaccine clinical trial was 19-23 days.

[c] The basis for this minimum interval is that the majority of participants in the Moderna COVID-19 vaccine clinical trial received the second dose 21 to 42 days after the first, as per the pre-defined window.

[d] The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.

Refer to Timing of Vaccine Administration in the CIG, Part 1 - Key Immunization Information for additional general information.

Extended intervals for COVID-19 vaccines to optimize early vaccine roll-out and population protection

Currently, no data on medium- or long-term efficacy of COVID-19 vaccines are available. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series, as delays between doses do not result in a reduction in final antibody concentrations for most multi-dose (prime-boost) products. For many other multi-dose vaccines provided in adulthood using other vaccine technologies, the greatest proportion of short-term protection is achieved with the first dose with additional doses primarily intended to extend protection over the longer term. However, the follow-up time in COVID-19 vaccine clinical trials is short, the duration of protection after one or both doses is unknown, and mRNA and viral vector-based vaccines represent relatively new vaccine technologies.

Morbidity and mortality from COVID-19 is ongoing. Extending the interval to the second dose of a COVID-19 vaccine maximizes vaccine supply to immunize the largest number of people as quickly as possible. Principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. Please refer to the NACI Advisory Committee Statement: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada in the context of limited vaccine supply for a summary of the evidence.

Follow-up of vaccine effectiveness in individuals for whom the second dose is delayed or who have otherwise missed their second dose (e.g., missed a follow-up immunization appointment) will be important to inform future recommendations and ensure completion of the vaccine series as soon as possible. NACI will continue to monitor the evidence and update recommendations as needed.

IV.4.2 Booster doses and re-immunization

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete. Given the emergence of VOC against which vaccine effectiveness may be decreased, additional vaccine doses may be necessary. NACI will continue to monitor the evidence and update recommendations as needed.

IV.4.3 Interchangeability

NACI recommends that the vaccine series be completed with the same COVID-19 vaccine product.

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Currently, no data exist on the interchangeability of COVID-19 mRNA vaccines. However, the spike proteins encoded by either of the authorized mRNA vaccines are stabilized in the same manner to remain in the pre-fusion conformation, though other vaccine components like the lipid nanoparticle and the mRNA sequence may be different. Currently, no data exist on the interchangeability of the AstraZeneca COVID-19 vaccine with other COVID-19 vaccines.

If the vaccine product used for a previously received dose is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g., complete a series started with an mRNA vaccine with another mRNA vaccine). In the context of limited COVID-19 vaccine supply and the absence of evidence on interchangeability of COVID-19 vaccines, the previous dose may be counted, and the series need not be restarted.

At this time, it is not recommended that vaccines of different types (e.g., mRNA vaccine and viral vector vaccine) be used in the same series, however, studies involving mixed schedules with different vaccines are ongoing. Recommendations on which vaccine product to complete a vaccine series in individuals who have received one dose of the AstraZeneca COVID-19 vaccine will be made immediately after evidence on mixed COVID-19 vaccine schedules is available (expected within 6 weeks). Active surveillance of effectiveness and safety of a mixed schedule are important and these recommendations may change as further evidence becomes available. Accurate recording of vaccines received will be critical. NACI will continue to monitor the evidence and update recommendations as needed.

Refer to Principles of Vaccine Interchangeability in the CIG, Part 1 - Key Immunization Information for additional general information.

IV.4.4 Post-vaccination counseling

NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.

Analgesics and antipyretics were used in clinical trials of COVID-19 vaccine for the management of pain and/or fever after vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.

All vaccine recipients should be instructed to seek medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the immunization clinic/venue.

All vaccine recipients who develop symptoms compatible with COVID-19 should be tested for SARS-CoV-2 to document breakthrough illness, particularly in the context of the emergence of VOC.

Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of the recently recognized adverse event of VITT and advised to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 20

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following receipt of the AstraZeneca vaccine (although most occur between days 4 and 14 post-vaccine) [16]. Symptoms to be vigilant for include: shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision, skin bruising (other than at the site of vaccination) or petechiae. In addition, healthcare professionals should be aware of VITT including how to diagnose and treat the condition (see Ontario Science Table guidelines).

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional information on pre- and post-vaccination counseling.

IV.5 Serological testing

Serologic testing is not needed before or after immunization with COVID-19 vaccine.

IV.6 Storage requirements

Pfizer-BioNTech COVID-19 vaccine

Frozen vials prior to use
The Pfizer-BioNTech COVID-19 vaccine must be stored at ultra-low temperatures of -80°C to -60°C and protected from light, in the original packaging, until ready to use.

Refer to the re-icing guidelines (available at CVDVaccine.ca) for instructions regarding the use of the manufacturer's original thermal container for temporary storage.

Vials may also be stored at -25°C to -15°C for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

Thawed, unpunctured vials (prior to dilution)
The Pfizer-BioNTech COVID-19 vaccine may be thawed and stored at +2°C to +8°C for up to 120 hours (5 days) or at room temperature (up to +25°C) for no more than 2 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

Do not refreeze thawed vials.

Thawed, punctured vials (after dilution)
The Pfizer-BioNTech COVID-19 vaccine must be stored between +2°C to +25°C and used within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.

Moderna COVID-19 vaccine

Frozen vials prior to use
The Moderna COVID-19 vaccine should be stored at temperatures of -25°C to -15°C and

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protected from light in the original packaging. Do not store on dry ice or below -40ºC.

Thawed, unpunctured vials
If not punctured, the Moderna COVID-19 vaccine can be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25ºC for up to 12 hours.

Do not refreeze thawed vials.

Thawed, punctured vials
The Moderna COVID-19 vaccine can be stored between +2ºC to below +25ºC but must be discarded after 6 hours from the time of first puncture.

AstraZeneca COVID-19 vaccine

Unopened multidose vial
The AstraZeneca vaccine can be stored between +2ºC to +8ºC and protected from light in the original packaging. Do not freeze.

Opened multidose vial
After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (up to +30ºC) or 48 hours in a refrigerator (+2ºC to +8ºC).

After the first puncture, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.

For more information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

IV.7 Simultaneous administration with other vaccines

NACI recommends that COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated).

Currently, no data exist on the simultaneous administration of COVID-19 vaccine with other vaccines. In the absence of evidence, attempts should be made to avoid simultaneous administration to maximize benefits of COVID-19 vaccination while minimizing any risks of harm, including the potential for immune interference or the erroneous attribution of an adverse event following immunization (AEFI) to a particular vaccine. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of

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at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine.

Refer to Timing of Vaccine Administration in the CIG, Part 1 – Key Immunization Information for additional general information on simultaneous administration of other vaccines.

IV.8 Vaccine safety and adverse events following immunization (AEFI)

Due to limitations in the number of participants and duration of follow-up from COVID-19 clinical trials, medium- and long-term evidence on vaccine safety is limited. However post-licensure vaccine pharmacovigilance is ongoing and safety signals around the world are detected and communicated globally. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, studies are ongoing.

The following section highlights key safety and AEFI data for the authorized and available COVID-19 vaccines. For additional details regarding trial design, including study population and length of follow-up, and safety for the vaccines authorized and available for use in Canada, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), and Appendix C (for the AstraZeneca COVID-19 vaccine). Refer to Appendix D for a summary of the frequency of AEFI for the different COVID-19 vaccine products.

Refer to Part 2 - Vaccine Safety in the CIG for definitions of AEFIs and additional general information.

IV.8.1 Very common and common adverse events

Common adverse events are defined as those that occur in 1% to less than 10% of vaccine recipients; very common adverse events occur in 10% or more of vaccine recipients. Please see Appendix D for a summary of adverse events identified in clinical trials of authorized, available COVID-19 vaccines.

Local

Pain at the injection site is very common after administration of the currently authorized, available COVID-19 vaccines. More than 40% of recipients experienced injection site pain. Redness and swelling are common or very common after administration. Localized axillary swelling and tenderness was a solicited adverse event in the Moderna COVID-19 clinical trial and was very common after administration with that vaccine. Local adverse events are usually mild or moderate and resolve within a few days of vaccination. For the authorized mRNA COVID-19 vaccines, pain at the injection site was slightly more frequent in younger adults compared to older adults. For AstraZeneca COVID-19 vaccine, local reactions were milder and reported less frequently after the second vaccine dose in all age groups.

Systemic

Fatigue, headache, muscle pain, chills, and joint pain are all either common or very common after the administration of the currently authorized, available COVID-19 vaccines. Fever was very

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common after administration of the second dose of the mRNA COVID-19 vaccines and common after any dose of AstraZeneca COVID-19 vaccine. More than a quarter of vaccine recipients experienced headache and/or fatigue after any dose. Systemic adverse events are usually mild or moderate intensity and resolve within a few days of vaccination. For the mRNA COVID-19 vaccines, systemic reactions are more frequent after the second vaccine dose and in younger adults. For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose than the first in all age groups.

IV.8.2 Uncommon, rare, and very rare adverse events

Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. The probability of detection of very rare adverse events in clinical trials is low given clinical trial population sizes; therefore, ongoing pharmacovigilance is essential.

To date, the available data does not indicate that vaccination of SARS-CoV-2 naïve individuals with authorized, available COVID-19 vaccines will elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 (e.g., vaccine-enhanced disease); however, further study is needed.

Lymphadenopathy was not a solicited adverse event in the Pfizer-BioNTech or AstraZeneca clinical trials (see Appendix D) but was uncommonly reported after administration of the Pfizer-BioNTech, and AstraZeneca COVID-19 vaccines.

No other solicited uncommon, rare, or very rare adverse events were reported among vaccinated participants in the clinical trials at this time.

Thrombosis and Thrombocytopenia following Vaccination with the AstraZeneca COVID-19 vaccine

Very rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported globally (with two cases reported out of over 700,000 doses of AstraZeneca COVID-19 vaccine administered in Canada as of April 17, 2021) following post-licensure use of AstraZeneca COVID-19 vaccine, usually between 4 and 14 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The exact mechanism by which the AstraZeneca COVID-19 vaccine may trigger VITT is still under investigation but the mechanism appears to be similar to spontaneous heparin-induced thrombosis (HIT) / autoimmune heparin-induced thrombosis, where antibodies to platelet factor 4 (PF4)-polyanion complexes induce platelet activation, which causes thrombosis and thrombocytopenia. This adverse event has not been identified following receipt of mRNA COVID-19 vaccines to date. The rate of this adverse event has been estimated to be between 1 per 26,000 and 1 per 500,000 people vaccinated with the AstraZeneca COVID-19 vaccine. The case fatality rate of VITT depends on prompt detection, diagnoses and treatment and is estimated to be between 21-60%. For more information, see Appendix C and NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.

IV.8.3 Guidance on reporting adverse events following immunization (AEFI)

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Vaccine providers are asked to report AEFIs through local public health departments and to follow AEFI reporting requirements that are specific to their province or territory. In general, any serious (defined as resulting in hospitalization, permanent disability or death) or unexpected adverse event that is temporally related to vaccination should be reported.

In addition to provincial or territorial reporting requirements, the Brighton Collaboration has developed a list of Adverse Events of Special Interest (AESI) that are of particular interest and should be reported. Refer to https://brightoncollaboration.us/covid-19/ for the list with definitions.

There may be additional very rare AEFIs that have not been detected through clinical trials to date.

Refer to Adverse Events Following Immunization (AEFI) in the CIG, Part 2 – Vaccine Safety for additional information on definitions, reporting, investigating and managing, and causality assessments for AEFIs.

Refer to Reporting Adverse Events Following Immunization (AEFI) in Canada for additional information on the completion and submission of AEFI reports.

IV.9 Contraindications and Precautions

Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines; investigations are ongoing to identify the allergen(s) responsible and the recommendations will be updated as evidence becomes available.

Table 4 lists potential non-medicinal ingredients in authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products. These reactions have occurred rarely, and ranged from mild cutaneous reactions to anaphylaxis. Anaphylaxis is typically a rare, severe, life-threatening allergic reaction usually with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include, but are not limited to: generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock. It is important to note that other, less serious reactions may mimic allergic reactions (e.g., vasovagal syncope) and vaccination is not contraindicated in these cases.

Refer to Anaphylaxis and other Acute Reactions Following Vaccination in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

Table 4. Ingredients of authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products

Vaccine product	Potential allergen included in the vaccine or its container	Other products where the potential allergen may be found*
Pfizer-BioNTech COVID-19 vaccine	polyethylene glycol (PEG) [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care

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		solutions, products such as ultrasound gel[d].
Moderna COVID-19 vaccine	PEG [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel[d].
	tromethamine[e] (trometamol or Tris)	Component in contrast media, oral and parenteral medications.
AstraZeneca COVID-19 vaccine	polysorbate 80[c]	medical preparations (e.g., vitamin oils, tablets, and anticancer agents), cosmetics[d,f]

N.B. This is not a complete list of products.

[a] Medications that contain PEG are described in Stone CA, et al., DOI:10.1016/j.jaip.2018.12.003

[b] A review of immediate type hypersensitivity reactions to PEG is available in Wenande et al, DOI: 10.1111/cea.12760

[c] There is a potential of cross-reactive hypersensitivity between PEG and polysorbates

[d] PEG is an additive in some food and drinks but allergic reactions to PEG in food or drinks have not been documented.

[e] One case report of anaphylaxis to tromethamine has been described (Lukawska et al, DOI: 10.1016/j.jaip.2018.08.035).

[f] Case reports of anaphylaxis to polysorbate 80 have been described (Badiu et al, DOI: 10.1136/bcr.02.2012.5797, Palacios Castaño et al, DOI: 10.18176/jiaci.0109).

Rare cases of VITT have been reported following immunization with the AstraZeneca viral vector vaccine. Investigations are ongoing and the recommendations will be updated as evidence becomes available. For more information, refer to Appendix C and NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.

Contraindications

An authorized COVID-19 vaccine should not be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector). If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e. individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine and individuals with anaphylaxis post viral vector vaccine may be offered a mRNA vaccine). If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization.

An authorized COVID-19 vaccine should not be routinely offered to individuals who are allergic to any component of the specific COVID-19 vaccine or its container. For a comprehensive list of components in each authorized COVID-19 vaccine and its container, please consult the corresponding product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.

Patients who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 vaccine should not receive a second dose of AstraZeneca COVID-19 vaccine.

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Precautions

If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided; vaccination may be considered in individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) after a previous dose of authorized COVID-19 vaccines or any of its components. Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if vaccination is chosen, an extended period of observation post-vaccination of at least 30 minutes should be provided for the aforementioned individuals.

Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.

In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.

Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from SARS-CoV-2 infection to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any persons are identified with symptoms on arrival at the venue, they should be instructed to follow current local public health measures.

As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, it would be prudent to wait until all symptoms of an acute illness are resolved before vaccinating with an authorized COVID-19 vaccine.

The safety and efficacy of authorized COVID-19 vaccines in pregnancy have not yet been established. Pregnant individuals were excluded from the mRNA and viral vector COVID-19 vaccine clinical trials. Currently, there are limited data on the safety of COVID-19 vaccine from

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animal developmental and reproductive toxicity studies. In rats that received the Moderna COVID-19 vaccine prior to or during gestation, no safety concerns regarding female reproduction, fetal/embryonal development, or postnatal development were demonstrated. According to a report presented to the European Medicines Agency (EMA), studies in rats using four full doses of the Pfizer-BioNTech COVID-19 vaccine did not indicate adverse effects with respect to fertility, pregnancy, embryo/fetal development, or postnatal development, up to day 21. Developmental and Reproductive Toxicity (DART) animal studies for the AstraZeneca COVID-19 vaccine are ongoing.

Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of the risk of VITT and advised to seek immediate medical attention if they develop symptoms of VITT.

Refer to Contraindications and Precautions in the CIG, Part 2 - Vaccine Safety for additional general information.

IV.10 Drug Interactions

There have been no drug interactions studies performed to date.

For more information about potential interactions with products containing anti-SARS-CoV-2 antibodies, refer to section IV.11 Blood products, human immunoglobulin and timing of immunization, in this Statement.

Tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)
There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.

In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent in order to avoid missing cases due to potentially false-negative results.

IV.11 Blood Products, Human Immunoglobulin and Timing of Immunization

NACI recommends that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. Therefore, timing of administration and potential interference between these two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines, which could prevent the production of antibodies stimulated by the vaccine.

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In the post-exposure setting, expert clinical opinion should be sought on a case-by-case basis when deciding whether anti-SARS-CoV-2 monoclonal antibodies would be appropriate to administer after receipt of COVID-19 vaccine, taking into consideration the risk of exposure and the risk of severe COVID-19 disease in the individual.

To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

V. RECOMMENDATIONS

Following the thorough review of available evidence summarized above, as well as the systematic assessment of ethics, equity, feasibility and acceptability considerations with the EEFA Framework [2] as summarized in NACI's Guidance on Key Populations for Early COVID-19 Immunization, NACI makes the following evidence-informed recommendations for public health program level decision-making for the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada.

NACI will continue to carefully monitor the scientific developments related to COVID-19 and COVID-19 vaccines, as well as ongoing vaccine pharmacovigilance, and will update recommendations as required.

Please note:

- A *strong recommendation* applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.
- A *discretionary recommendation* may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

Please see Table 6 for a more detailed explanation of the strength of NACI recommendations.

RECOMMENDATIONS ON AUTHORIZED, AVAILABLE COVID-19 VACCINES

These recommendations apply only to COVID-19 vaccines currently authorized and currently available for use in Canada (Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine; AstraZeneca COVID-19 vaccine). In considering these recommendations and for the purposes of publicly funded program implementation, provinces and territories may consider local programmatic factors (e.g., logistical and operational contexts, resources) and local epidemiology (e.g., transmission of SARS-CoV-2 VOC).

1. **NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered.**

(Strong NACI Recommendation)

2. **NACI recommends that a complete series with the AstraZeneca COVID-19 vaccine may be offered to individuals without contraindications in select age ranges* in areas where**

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COVID-19 activity is high or very high ONLY if the individual does not wish to wait for an mRNA vaccine AND ALL of the following conditions apply:

a) The benefit-risk analysis** determines that the benefit of earlier vaccination with the AstraZeneca COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
b) As part of benefit-risk analysis, the following is considered (in addition to other factors)**: The risk of severe outcomes of COVID-19 decreases with decreasing age. In age groups younger than 50 years of age, the benefit provided by offering AstraZeneca COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty; AND
c) The benefits and relative risk** and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND
d) There will be substantial delay to receive an mRNA vaccine.

Note: AstraZeneca COVID-19 vaccine should not be offered in areas of very low, low, or moderate COVID-19 activity.

(Discretionary NACI Recommendation)

***Decision tool to help identify in which age ranges the AstraZeneca COVID-19 vaccine may be considered (in the context of other factors considered in the Risk Assessment Framework**)**

Local COVID-19 activity	Age range where the benefit of AstraZeneca COVID-19 vaccine may outweigh the risk
High (≥3 COVID-19 cases/ 10,000 per day)	50 years and older
Very High (≥6 COVID-19 cases/10,000 per day)	40 years and older

Please see Appendix E for details, limitations, and uncertainties

**See Risk Assessment Framework below and Management Options Table (Section V.I) to assist with this determination

****Risk Assessment Framework for the use of AstraZeneca COVID-19 vaccine**

The benefit-risk analysis for who to consider offering the AstraZeneca COVID-19 vaccine to while an authorized mRNA COVID-19 vaccine is temporarily unavailable or inaccessible may vary between jurisdictions and individuals and will depend on:

- **Local COVID-19 epidemic conditions** (e.g., consider offering available AstraZeneca COVID-19 vaccine to individuals in regions of high or very high epidemic transmission where immediate protection is needed to prevent symptomatic disease and preserve health system capacity, carefully considering the local transmission potential for viral variants of concern and anticipated protection against them.)
- **Local vaccine supply** (e.g., consider how long an individual will need to wait to be offered an mRNA vaccine, based on available and expected vaccine supply.)
- **Risk of severe illness and death** (e.g., consider offering available AstraZeneca COVID-19 vaccine to individuals at risk of severe illness and death who do not wish to wait to receive mRNA vaccine. The risk of severe outcomes of COVID-19 decreases as age decreases. In age groups younger than 50 years, the benefit provided by offering AstraZeneca COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty.)

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- **Risk of exposure** (e.g., consider offering the available AstraZeneca COVID-19 vaccine to individuals at increased risk of exposure to SARS-CoV-2 due to inability to physically distance or reduced access to infection prevention and control measures who do not wish to wait to receive an mRNA vaccine.)
- **Logistical considerations** (e.g., although the AstraZeneca COVID-19 vaccine is refrigerator-stable, which makes this vaccine easier to store and handle, infrastructure now exists to support the use of ultra-frozen and frozen mRNA vaccines.)
- **Risk of Vaccination-Induced Immune Thrombotic Thrombocytopenia** (e.g., the rate of this adverse event is estimated to be between 1/26,000 and 1/500,000 vaccinated with the AstraZeneca COVID-19 vaccine. The case fatality rate depends on prompt detection, diagnoses and treatment and is estimated to be between 21 and 60%. Other predisposing factors for VITT are unclear. NACI continues to monitor evolving evidence.)
- **Vaccine characteristics** (e.g., limited data suggests that all authorized, available vaccines offer protection against hospitalization and likely also death from COVID-19. Results from clinical trials of mRNA vaccines suggest superior efficacy against symptomatic COVID-19 disease compared to the AstraZeneca vaccine. There is evidence that both the Pfizer-BioNTech and AstraZeneca vaccines protect against the B.1.1.7 SARS-CoV-2 variant. In studies in South Africa, the AstraZeneca vaccine did not offer protection against the B.1.351 SARS-CoV-2 variant. Early evidence suggests that the Pfizer-BioNTech vaccine has moderate to high effectiveness against asymptomatic infection, with some evidence available for Moderna as well.)
- **Access to diagnosis and treatment for COVID-19 or VITT** (e.g., consider healthcare system capacity, access to tertiary and ICU care, as well as IVIG for treatment of VITT.)
- **Risk of exacerbating inequities** (e.g., the use of the AstraZeneca COVID-19 vaccine may increase inequities for individuals with limited ability to reduce their personal risk of infection or who work in occupations with direct close physical contact with the public, and due to the complexities of making an informed choice with regard to the risk and benefits of earlier vaccination with the AstraZeneca COVID-19 vaccine. Consider the impact of exacerbating inequities in these populations, many of whom belong to marginalized and disadvantaged groups disproportionately affected by the pandemic.)

Refer to the Management Options Table for COVID-19 vaccines authorized and available for use in Canada (Section V.I) for a summary of evidence and factors for jurisdictions to consider when implementing COVID-19 immunization programs.

Summary of evidence and rationale:

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption. The COVID-19 immunization program should be rolled out as efficiently, effectively and equitably as possible.
- mRNA COVID-19 vaccines are authorized in individuals 16 years of age and older (Pfizer-BioNTech COVID-19 vaccine) and in individuals 18 years of age and older (Moderna COVID-19 vaccine). A non-replicating viral vector vaccine is authorized and available for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine).
- A complete series for all currently authorized and available COVID-19 vaccines is two doses.
- See Table 1 for risk factors associated with increased risk of severe outcomes from COVID-19 and increased risk of exposure to COVID-19. Please refer to NACI's Guidance on the prioritization of key populations for COVID-19 immunization for additional details

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on sequencing of key populations, including a comprehensive analysis of ethical, equity, feasibility and acceptability considerations.

mRNA COVID-19 vaccines

- Clinical trial data available to date have shown that the currently authorized mRNA COVID-19 vaccines are highly efficacious (94 to 95%) in preventing confirmed symptomatic COVID-19 disease in the short term from one to two weeks after receiving the full two-dose series.
- Highest efficacy and maximum immune response were observed after the second dose. Efficacy of a two-dose series was consistent across age groups. Estimates of vaccine effectiveness of the Pfizer-BioNTech vaccine were comparable in countries where the predominant circulating strain was the B.1.1.7 VOC first identified in the UK. Local and systemic adverse events were generally less frequent in older adults (≥56 in the Pfizer-BioNTech clinical trial and ≥65 in the Moderna clinical trial). The authorized mRNA vaccines are similarly safe and efficacious in those with one or more comorbidities (e.g., body mass index ≥30 kg/m^2, chronic pulmonary disease, diabetes mellitus, cardiac disease).

AstraZeneca COVID-19 vaccine

- Combined evidence from clinical trial and observational study data available to date have shown that the AstraZeneca COVID-19 vaccine offers protection against symptomatic COVID-19 disease and hospitalization in adults ≥18 years of age after receiving at least one dose.Clinical trial data available to date have shown that the AstraZeneca COVID-19 vaccine has demonstrated moderate efficacy against symptomatic, confirmed COVID-19 of approximately 62% in those 18-64 years of age. Efficacy of a two-dose series increased to approximately 82% when the interval between doses was 12 weeks or more. In adults 65 years of age and over, observational data from the UK of vaccine effectiveness after one dose have shown a reduction in the risk of symptomatic disease and hospitalization. The highest efficacy with the authorized regimen of AstraZeneca COVID-19 vaccine was seen in clinical trial groups that had a longer interval between doses. Clinical trials suggest that vaccine efficacy increases with extended intervals between the first and second dose of vaccine, with a maximum reduction in risk of symptomatic disease observed at 12 weeks or more following the priming dose. Data suggest AstraZeneca vaccine has a vaccine efficacy of 74.6% against the B.1.1.7 VOC first identified in the UK (compared to 84.1% against the non-B.1.1.7 strain). Published data suggests a vaccine efficacy of 10.4% against mild to moderate illness from the B.1.351 VOC first detected in South Africa. In clinical trials, the majority of local and systemic adverse events with the AstraZeneca COVID-19 vaccine were mild and transient and did not differ by dose administered or age. Rare but serious cases of blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported globally (with two cases reported out of over 700,000 doses of AstraZeneca COVID-19 vaccine administered in Canada as of April 17, 2021) following post-licensure use of AstraZeneca COVID-19 vaccine, usually between 4 and 14 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The exact mechanism by which the AstraZeneca COVID-19 vaccine may trigger VITT is still under investigation. A case fatality rate of between 21 and 60% has been reported.
- AstraZeneca COVID-19 vaccine is similarly efficacious in those with one or more mild to moderate and controlled medical conditions (e.g., cardiovascular disease, respiratory disease, diabetes, body mass index ≥30 kg/m2).

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mRNA COVID-19 vaccines versus AstraZeneca COVID-19 vaccine

NACI reviewed the recent epidemiology of COVID-19 in Canada (including circulation of variants), vaccine characteristics (including efficacy, effectiveness, safety), evidence and international guidance on VITT, anticipated vaccine supplies, Health Canada's assessment of COVID-19 vaccines, as well as a comprehensive analysis of the implications on ethics, equity, feasibility and acceptability [2] of its recommendations for the use of COVID-19 vaccines in Canada. NACI assessed the risk of developing and dying from VITT compared to COVID-19 ICU admissions and deaths that could be prevented by an early dose of AstraZeneca vaccine (instead of waiting for an mRNA vaccine given Canada's expected vaccine supply) by age across various COVID-19 epidemiologic scenarios (very low, low, moderate, high, very high activity). Please see Appendix E for details and limitations. Given the low numbers of events reported for VITT, there is a high level of uncertainty in the incidence of this adverse event by age group. Initial data suggested there may be a trend for increasing incidence of VITT with decreasing age, but this could be due to differences in reporting and vaccination with AstraZeneca in different age groups. While the epidemiology of COVID-19 may evolve with the circulation of VOCs, evidence to date reveals the risk of severe disease associated with COVID-19 increases with age, with younger adults at lower risk of hospitalization and death. NACI will continue to monitor the epidemiology of COVID-19 and reassess these recommendations as mRNA COVID-19 vaccine supply increases.

Upon analysis of the information available, NACI concluded that given an expected increase in mRNA vaccine supplies and their associated timelines, the differences in the epidemiology and risk of COVID-19 across Canada and between populations, and because of the evolving evidence for VITT, there is uncertainty in the evidence of advantages and disadvantages of the use of AstraZeneca COVID-19 vaccine in vaccine programs for all Canadians. On the other hand, the advantages of highly efficacious mRNA COVID-19 vaccines, with no safety signals of concern to date, clearly outweigh any possible disadvantages for most populations, and NACI made a strong recommendation for the preferential use of mRNA COVID-19 vaccines. In the context of increasing mRNA vaccine supplies and ongoing pandemic disease, NACI made a discretionary recommendation on the use of AstraZeneca COVID-19 vaccine in select age ranges in areas where COVID-19 activity is high (≥ 3 COVID-19 cases/10,000 per day) or very high (≥ 6 COVID-19 cases/10,000 per day) for individuals who do not wish to wait for an mRNA vaccine and only if certain conditions are met (including a benefit-risk analysis, informed consent, and substantial delay for receipt of an mRNA vaccine). NACI summarized various factors (in addition to age) to consider to facilitate a benefit-risk analysis in its Risk Assessment Framework for the use of AstraZeneca COVID-19 vaccine. As demonstrated in Appendix E, the rate of death from COVID-19 potentially prevented by the AstraZeneca COVID-19 vaccine may be higher than the rate of death from VITT in areas of high COVID-19 activity in those 50 years of age and older, and in areas of very high COVID-19 activity in those 40 years of age and older, in some circumstances (considering other individual risk factors such as risk of exposure, summarized in the Risk Assessment Framework). NACI cautions that in age groups younger than 50 years of age, the benefit of offering AstraZeneca COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty, and this vaccine should not be offered to individuals in any age group in areas with very low, low, or moderate COVID-19 activity.

A summary of the evidence and rationale for NACI's strong preferential recommendation for the use of mRNA COVID-19 vaccines in population-level programs and discretionary recommendation for the use of the AstraZeneca COVID-19 vaccine for individuals who do not wish to wait for an mRNA vaccine is below:

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- **Epidemiology**: The epidemiology and risk of COVID-19 vary across Canada and between populations. The incidence of cases due to VOC in Canada is increasing, particularly among younger individuals, but differences in risk for severe outcomes due to VOC by age group have yet to be determined. NACI will continue to monitor the evolving epidemiology.
- **Efficacy and Effectiveness**: Emerging data suggests that all authorized, available vaccines offer protection against hospitalization and likely also death from COVID-19. In clinical trials, mRNA COVID-19 vaccines demonstrated higher efficacy than was shown for the AstraZeneca COVID-19 vaccine.
- **Safety and VITT**: Evidence on the association between VITT following vaccination with the AstraZeneca COVID-19 vaccine is evolving but the association has been confirmed. Several countries have paused the AstraZeneca COVID-19 vaccination program while others have restricted its use to certain age groups (from 30 years and over to 70 years and over). No clear pattern or risk factors have been identified to date among cases of VITT.
- **Public health benefit-risk assessment:** An age-based benefit-risk analysis was conducted to determine if the benefit of earlier vaccination with the AstraZeneca COVID-19 vaccine (instead of waiting for an mRNA vaccine) outweighs the risk of harms from VITT across various levels of COVID-19 activity (very low, low, moderate, high, very high). At the time the analysis was conducted, the risk of severe COVID-19 outcomes (such as death) exceeded the risk of VITT in adults 50 to 69, only in areas of high or very high epidemiology. The benefits of earlier vaccination with AstraZeneca COVID-19 vaccine were less clear in younger age groups in these areas. A benefit-risk assessment was not completed for adults 70 years or older as mRNA vaccine is already available to this age group in Canada. Refer to Appendix E for details on, and limitations of, this analysis.
- **Ethics**: NACI consulted with the Public Health Ethics Consultative Group (PHECG) on the ethical considerations for restricting the use of the AstraZeneca vaccine in the current and anticipated pandemic and vaccine supply context. The PHECG provided recommendations in the following areas: promoting well-being and minimizing risk of harm, maintaining trust, respect for persons and fostering autonomy, and promoting justice and equity. NACI integrated these recommendations into its guidance (e.g., enabling respect for persons and autonomy by incorporating informed consent into the discretionary recommendation for use of AstraZeneca vaccine; promoting justice and equity by specifically identifying risks to exacerbating inequities in the Risk Assessment Framework).
- **Equity**: NACI examined the implications of various recommendation options on the opportunity for all populations to have a fair opportunity to attain their full health potential [(2)]. Populations that receive the AstraZeneca COVID-19 vaccine may have protection against COVID-19 disease earlier than if they had waited for mRNA vaccines to be available. However, these populations may ultimately have lower protection, as a larger proportion of the vaccinated population will remain susceptible. NACI considered the impact of the provision of a less efficacious vaccine with a safety signal of concern to marginalized and disadvantaged populations who have been disproportionately affected by the pandemic, and whose lived experience may have led to distrust of governments. Depending on vaccination strategies, this could potentially exacerbate health inequities if this potential harm is not considered when implementing the vaccine program in populations who experience intersecting risk factors for severe disease and exposure (e.g., racialized populations living in multigenerational housing with over-representation in jobs providing essential services such as food and healthcare). The risk of COVID-19 to individuals and their families who have limited ability to reduce their personal risk of

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infection or who work in occupations with direct close physical contact with the public, the anticipated waiting time for an mRNA vaccine, and the individual's risk tolerance to wait for an mRNA vaccine should be considered. This may vary across Canada and between populations, so the Risk Assessment Framework may be used to assist with decision-making.

- **Feasibility**: NACI considered the impact of its recommendations on the successful implementation of COVID-19 immunization programs in the local setting with available resources [2]. Canada has procured and is expecting enough supply of mRNA vaccines to enable vaccination of currently eligible Canadian population before fall 2021, with enough supply to enable all eligible Canadians to receive their first dose by June 2021. Expected supplies of AstraZeneca COVID-19 vaccines for Canada are minimal in comparison to expected supplies of mRNA vaccines in the coming weeks. Therefore, the anticipated waiting time to receive an mRNA vaccine will soon be reduced but may vary between populations and across jurisdictions. While the mRNA COVID-19 vaccines have more challenging storage and transportation requirements than the AstraZeneca COVID-19 vaccine, infrastructure now exists to support the use of ultra-frozen and frozen mRNA vaccines.
- **Acceptability**: NACI reviewed recent Canadian data to consider the potential impact of its recommendations on intention and behaviours toward COVID-19 vaccination. The desire to be vaccinated continues to rise. However, various populations who have been disproportionately affected by the pandemic are also more hesitant or experience barriers in receiving a COVID-19 vaccine (e.g., racialized populations, migrant or undocumented workers). While public opinion research conducted in March suggested 44-60% of Canadians had no preference on which vaccine they received, surveys conducted in April found that Canadians who are planning to get vaccinated are far more comfortable with the mRNA vaccines (90-92%) than the AstraZeneca vaccine (41%) [17]. Data collected over the course of the pandemic have consistently found that Canadians cite "ensuring the safety of the vaccine" as the main reason for delaying or not getting COVID-19 vaccination. NACI transparently summarized the best available evidence (including knowns and unknowns) to develop its evidence-informed expert guidance and enhance trust and confidence in its recommendations.

3. **Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine *up to four months* after the first. Second doses should be offered as soon as possible after all eligible populations have been offered first doses, with priority given to those at highest risk of severe illness and death from COVID-19 disease. Vaccinated people (with one or two doses) should continue to follow recommended public health measures. NACI will continue to monitor the evidence on effectiveness of an extended dose interval and will adjust recommendations as needed. *(Strong NACI Recommendation)***

Jurisdictions may choose to shorten the time between the first and second dose of a two-dose series for COVID-19 vaccines in specific population groups based on their local epidemiology, vaccine supply and vaccine delivery mechanisms.

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Summary of evidence and rationale:

- Morbidity and mortality from COVID-19 is ongoing and vaccine supply is limited. Extending the interval to the second dose allows vaccination of the largest number of people as quickly as possible, providing more people with direct protection and the possibility of indirect and community protection.
- An extended interval of up to four months allows as many eligible populations as possible to be offered vaccination with one dose before proceeding to offer second doses. However, as soon as all eligible groups have been offered their first dose of vaccine, second doses should be offered. The interval between first and second dose should not be extended any longer than needed to offer first doses of vaccine to all eligible individuals.
- This recommendation applies to all two-dose COVID-19 vaccines currently authorized for use and available in Canada.
- Current evidence suggests very good vaccine efficacy against symptomatic COVID-19 from one dose of COVID-19 vaccines, with good effectiveness shown in observational studies (generally between 60 and 80%, with some lower and higher estimates) against symptomatic disease and/or asymptomatic infection, as well as very good effectiveness against hospitalization (approximately 80%) and death (approximately 85% based on one study from the UK). While two doses of mRNA vaccines have shown excellent efficacy and effectiveness, one dose of mRNA vaccines appear to perform similarly to one or two doses of the AstraZeneca vaccine.
- Effectiveness has been documented for up to two months after the first dose of the mRNA vaccines, and the AstraZeneca clinical trial publication modelled one-dose efficacy up to 90 days after vaccination.
- Informed expert opinion based on principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.
- In situations where informed consent included assumptions about second dose timing, jurisdictions may consider offering second doses at shorter intervals for those who provided consent for the vaccine series prior to implementation of this recommendation.
- Because of ongoing disease transmission and less than complete individual protection from vaccination in either one-dose or two-dose vaccinated people, ongoing compliance with public health measures (masking, physical distancing and limiting social interactions as per public health guidance) should continue at this time.
- The vaccine effectiveness of the first dose will be monitored closely and the decisions regarding the second dose will be continuously assessed based on surveillance and effectiveness data and post-implementation study designs. In addition, effectiveness against variants of concern will also be monitored closely. If indicated based on these data, recommendations will be revised to offer earlier second doses to some cohorts or population groups.

Please see NACI's Statement on Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada in the context of limited vaccine supply for a summary of the evidence and further rationale for this recommendation.

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4. **NACI recommends that all individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.** ***(Strong NACI Recommendation)***

Summary of evidence and rationale

- Currently, there is insufficient evidence on the duration of protection of COVID-19 vaccines and the effectiveness of COVID-19 vaccines in reducing transmission of SARS-CoV-2. Evidence of protection against asymptomatic SARS-CoV-2 infection is emerging for the mRNA vaccines, but the evidence is insufficient at this time to recommend discontinuation of public health measures. NACI will continue to monitor the evidence and update recommendations as needed.
- Although effectiveness against symptomatic disease and/or asymptomatic infection appears to be very high for two doses of mRNA vaccines (~90-95%), some individuals will still remain susceptible even after two doses of vaccine. One dose of an mRNA vaccine and one or two doses of the AstraZeneca vaccine have good, but somewhat lower, effectiveness, and does not appear to protect against asymptomatic infection based on clinical trial results. Therefore adherence to public health measures in vaccinated individuals (one or two doses) remains very important at this time when SARS-CoV-2 continues to circulate widely.
- Evidence of protection offered by COVID-19 vaccines against VOC is evolving (see Table 5).
- There is evidence to support the effectiveness of other recommended public health measures in pre-exposure and post-exposure scenarios, including physical distancing, masking, hand hygiene, as well as isolation and quarantine.
- Currently, there is no evidence on the use of COVID-19 vaccine for post-exposure prophylaxis.
- Federal, provincial/territorial, and local public health measures for the prevention and control of SARS-CoV-2 should continue to be followed.

5. **NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection.** ***(Discretionary NACI Recommendation)***

Summary of evidence and rationale:

- Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.
- Currently, there is a lack of evidence on potential differences in vaccine efficacy or safety between those with and without prior evidence of SARS-CoV-2 infection. In COVID-19 vaccine clinical trials to date, individuals with PCR-confirmed SARS-CoV-2 were excluded and there were only a small number of trial participants with serologic evidence of previous infection (IgG+) who had confirmed symptomatic COVID-19 during the trials, therefore efficacy in this population is uncertain.
- The immune response to SARS-CoV-2, including duration of immunity, is not yet well understood. Reinfections with SARS-CoV-2 have been reported and research to establish the severity, frequency, and risk factors of reinfection with SARS-CoV-2 is ongoing.
- In the context of limited supply, to allow for the protection of a larger number of at-risk individuals, vaccination with a COVID-19 vaccine may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first

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three months following infection. However, if challenging from a feasibility perspective, jurisdictions may elect to disregard prior PCR-confirmed SARS-CoV-2 infection status and vaccinate everyone in a given target group.

- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, and to minimize the risk of transmission of COVID-19 at an immunization venue, NACI recommends that it is prudent to wait until all symptoms of an acute illness are completely resolved before vaccinating with COVID-19 vaccine, as well as ensuring that the individual is no longer considered infectious based on current criteria.
- NACI will continue to monitor the evidence regarding vaccination in those previously infected with SARS-CoV-2 and will update recommendations as needed.

NACI also makes the following recommendations for COVID-19 immunization in some specific populations who were either excluded from or were represented by small numbers of participants in clinical trials. Vaccine may be offered to some individuals in these populations in some circumstances on a case-by-case basis with a risk-benefit analysis (where the risk of exposure and/or severe COVID-19 disease outweighs the risk of vaccination), and with transparency about the insufficiency of evidence. Preference for mRNA COVID-19 vaccine (as outlined in Recommendation #1, above), if available, also applies to the populations described below. These recommendations may change as more evidence becomes available.

Immunosuppressed persons

6. NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (*Discretionary NACI Recommendation*)

Summary of evidence and rationale

- Currently, there is limited evidence that immunosuppression is an independent risk factor for severe COVID-19, though evidence is evolving. A rapid review of evidence from OECD member countries found a low certainty of evidence for no association with mortality or hospitalization due to COVID-19 in those with unspecified immunosuppression [5]. The review found a low certainty of evidence for at least a two-fold increase in mortality due to COVID-19 for those with sickle cell disease or severe immunodeficiency; metastatic cancer; chemotherapy in the past 12 months or radiotherapy in the past 6 months; solid organ, bone marrow, or stem cell transplant. Caution should be taken when interpreting low certainty evidence. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found.
- Currently, there are no data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial.

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- No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials.
- The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- In general, non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to the authorized COVID-19 vaccines.
- People living with HIV who are considered immunocompetent may be vaccinated.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization of Immunocompromised Persons in the CIG, Part 3 – Vaccination of Specific Populations for definitions and additional general information.

Persons with an autoimmune condition

7. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in these populations. (*Discretionary NACI Recommendation*)**

Summary of evidence and rationale

- The evidence that having an autoimmune condition is an independent risk factor for severe COVID-19, is evolving. A rapid review of evidence from OECD member countries found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with type 1 diabetes, as well as with a group of neurological disorders including multiple sclerosis and myasthenia gravis. The review found a low certainty of evidence of little or no association with mortality and a moderate certainty of evidence for little or no association with hospitalization from COVID-19 in those with rheumatoid arthritis, rheumatic disease, or systemic lupus erythematosus. Caution should be taken when interpreting low certainty evidence [5]. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found.
- Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.
- The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying

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condition, the severity and progression of disease, and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.

- Other applications of mRNA technologies have been for the treatment of cancer, which requires an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk; however, further evaluation is needed.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Persons with Chronic Diseases in the CIG, Part 3 – Vaccination of Specific Populations for additional general information on autoimmune conditions.

Pregnancy and Breastfeeding

8. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)**

9. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)**

Summary of evidence and rationale

- The evidence of pregnancy as an independent risk factor for severe COVID-19 is evolving. A rapid review of evidence from OECD member countries found a low certainty of evidence of at least a two-fold increase in hospitalization due to COVID-19 for pregnancy (any stage). Caution should be taken when interpreting low certainty evidence [5]. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found
- Currently, there are no data on the safety and efficacy of COVID-19 vaccines in pregnancy or during breastfeeding. Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 vaccine clinical trials.
- Currently, there are no data to inform outcomes of inadvertent administration of COVID-19 vaccine to pregnant individuals or their developing fetus in clinical trials. Outcomes in participants who became pregnant during the clinical trials and fetal outcomes will be reported through registries and NACI will reconsider recommendations when these data become available.
- It is unknown whether the vaccines are excreted in human milk, but there are no data on outcomes in breastfeeding individuals or their breastfed infants. There have been no

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theoretical concerns about these vaccines in breastfeeding individuals or their breastfed infants.

- Currently, there are limited data on the safety of COVID-19 vaccine from animal developmental and reproductive toxicity studies. In rats that received the Moderna COVID-19 vaccine prior to or during gestation, no safety concerns regarding female reproduction, fetal/embryonal development, or postnatal development were demonstrated. According to a report presented to the European Medicines Agency (EMA), studies in rats using four full doses of the Pfizer-BioNTech COVID-19 vaccine did not indicate adverse effects with respect to fertility, pregnancy, embryo/fetal development, or postnatal development, up to day 21. .Developmental and Reproductive Toxicity (DART) animal studies for the AstraZeneca COVID-19 vaccine are ongoing.
- Individuals who are pregnant, breastfeeding, or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers) and/or at increased risk of severe COVID-19 disease (e.g., due to pre-existing medical condition, body mass index of 40 or more) and may wish to be vaccinated despite the lack of evidence of COVID-19 vaccination in pregnancy or during breastfeeding in order to protect themselves. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception. In the face of scientific uncertainty, it may be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of a COVID-19 vaccine. A COVID-19 vaccine may be administered any time after pregnancy.
- Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received a COVID-19 vaccine.
- If pregnancy is determined after initiation of the vaccination series, completion of the series may be delayed until after pregnancy, unless risk factors for increased exposure or severe COVID-19 are present and informed consent for vaccination is obtained as above. NACI also encourages additional research and surveillance of COVID-19 vaccination in pregnancy.
- Eligible individuals should be offered a complete vaccine series with an authorized COVID-19 vaccine post-partum and prior to attempting pregnancy so that the recommended interval between completion of the vaccine series and conception is maintained. It should be noted that at this time the AstraZeneca COVID-19 vaccine is not recommended for those under 55 years of age as the safety signal for VITT is investigated.
- Vaccine recipients and health care providers are encouraged to report COVID-19 vaccine during pregnancy or breastfeeding to the local public health authority as well as to the vaccine manufacturer for follow-up. Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Pregnancy and Breastfeeding, Part 3 – Vaccination of Specific Populations of the CIG for additional general information.

Children and Adolescents

10. NACI recommends that COVID-19 vaccines should not be offered routinely to individuals who are not in the authorized age group. *(Strong NACI Recommendation).*

a. However, a complete vaccine series with a Pfizer-BioNTech may be offered to individuals 12-15 years of age who are at very high risk of severe outcomes of

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COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) or are at increased risk of exposure (e.g., due to living in a congregate care facility), if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent with the individual and the parent or guardian includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in this population. ***(Discretionary NACI Recommendation)***

Summary of evidence and rationale

- Evidence to date suggests that in general, children infected with SARS-CoV-2 are not at increased risk of severe disease. A rapid review of evidence from OECD member countries found a low certainty of evidence of at least a two-fold increase in hospitalizations due to COVID-19 among children (≤18 years of age) with obesity, hypertension, or immunodeficiency, compared to children without these conditions. Caution should be taken when interpreting low certainty evidence.
- Evidence on COVID-19 vaccination in those less than 12 years of age is absent, and only limited clinical data on the use of the Pfizer-BioNTech COVID-19 vaccine in those aged 12 to 15 years is available. The Moderna COVID-19 vaccine and AstraZeneca COVID-19 vaccine clinical trial results have to date only included adults 18 years of age and older. Clinical trials in children less than 18 years of age have been initiated and are ongoing; NACI is monitoring the evidence and will update recommendations when results become available.
- For adolescents with certain pre-existing medical conditions compounded by an increased risk of exposure to SARS-CoV-2 (e.g., due to living in a congregate setting such as a group home), the balance of risks and benefits of vaccination with a COVID-19 vaccine must be made on a case-by-case basis.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

NACI continues to recommend the following:

- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.

- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded/remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions

- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, seniors living in congregate care settings, children and adolescents) is recommended. Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is

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ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.

Refer to Vaccine Safety and Pharmacovigilance in the CIG, Part 2 – Vaccine Safety for additional information.

NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization**:**

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.

- Jurisdictions should ensure close and rapid monitoring of safety, effectiveness, and coverage of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.

- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

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V.I MANAGEMENT OPTIONS FOR COVID-19 VACCINES AUTHORIZED AND AVAILABLE FOR USE IN CANADA

There are currently three authorized COVID-19 vaccines that are available in Canada for the prevention of symptomatic COVID-19 that use two different vaccine platforms. To assist with the decision on which vaccine to offer to different populations or groups, a comparison of the relative merits of both have been summarized in Table 5 below. Caution should be taken when comparing vaccines due to differences in studies conducted for each vaccine (e.g., different endpoints, different analyses, different time periods/countries and circulating strains)

Table 5. Management options for types of COVID-19 vaccines authorized and available for use in Canada

Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
Efficacy and Effectiveness	**Efficacy against symptomatic illness after a complete series** • Pfizer-BioNTech vaccine is overall 94% efficacious ≥14 days after dose 2 in study participants 18 years of age and older. Data suggests the Pfizer/BioNTech vaccine is 95% efficacious in participants ≥65 years of age 7 or more days after dose 2. • Moderna vaccine is overall 94% efficacious in participants 18 years of age and older ≥14 days after dose 2. • Data suggests the Moderna vaccine is 86% efficacious in individuals ≥65 years of age ≥14 days after dose 2. **Effectiveness against symptomatic illness and hospitalization** • Current data from real-world studies suggests that mRNA COVID-19 vaccines provide good protection against COVID-19 hospitalization >14 days after the first dose, including in older populations (≥65 years). • Data from real-world studies provide some evidence that the first dose of mRNA COVID-19 vaccines provide very good protection against COVID-19-related death.	**Efficacy against symptomatic illness after a complete series** • AstraZeneca SD/SD vaccine is 62% efficacious in participants 18 to 64 years of age. • Current data from clinical trials are insufficient to determine the efficacy of the AstraZeneca vaccine in individuals ≥65 years of age. • The interval between the first and second dose of the AstraZeneca vaccine may impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. **Effectiveness against symptomatic illness and hospitalization** • Observational data in individuals ≥65 years of age have shown a reduction in the risk of symptomatic disease and hospitalization with one dose of AstraZeneca vaccine.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
	• Limited data from real-world studies suggests the Pfizer-BioNTech COVID-19 vaccine has high vaccine effectiveness >7 days after the second dose against severe disease and COVID-19 related hospitalization. • Effectiveness data on the Moderna COVID-19 vaccine alone is not currently available.	
	Efficacy against asymptomatic infection • A preliminary analysis of limited data in an ongoing trial suggests the Moderna COVID-19 vaccine may be efficacious in preventing asymptomatic infection, however data is still being collected and the final analysis is not complete. **Effectiveness against asymptomatic infection** • Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose (depending on time since vaccination) and high after the second dose [9, 14]. Similar results were reported for mRNA COVID-19 vaccines in general [15].	**Efficacy against asymptomatic infection** • An exploratory ad hoc analysis of limited data suggests the AstraZeneca vaccine may not be efficacious in preventing asymptomatic infection.
	Re-vaccination • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern. • Re-vaccinating those who initially received an mRNA vaccine with the same or another mRNA vaccine is currently being investigated. • The efficacy and safety of re-vaccinating those who initially received mRNA vaccine with a different COVID-19 vaccine are unknown at this time but are being investigated.	**Re-vaccination** • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern • Re-vaccination with a booster dose of the AstraZeneca vaccine may reduce vaccine effectiveness due to the possible development of immunity to the viral vector which may interfere with the immune response to subsequent doses. However, this is still being investigated. • The efficacy and safety of re-vaccinating those who initially received AstraZeneca vaccine with a different COVID-19 vaccine are unknown at this time.
	Humoral response	**Humoral response**

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
Immunogenicity	• Humoral responses for both mRNA COVID-19 vaccines peaked after a second dose, including elicitation of neutralizing antibodies. However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with protection. • Humoral responses had similar trends in individuals 18 to 55 years of age and individuals 65 to 85 years of age.	• Humoral responses peaked after a second dose, including elicitation of neutralizing antibodies, for seronegative vaccine recipients. For seropositive vaccine recipients, humoral responses peaked at the first dose and maintained or decreased at the second dose. • For the AstraZeneca vaccine, humoral responses were lower in individuals ≥65 years of age and older, compared to individuals 18 to 64 years of age in unpublished data presented to NACI. Conflicting results have been shown for other age groups in recently published data [18]. • However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with vaccine protection.
	Cellular response • Both mRNA vaccines have been shown to produce a cellular immune response by one to two weeks after administration of a second dose. • Increases in cellular immune responses response were seen in both younger and older adults. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.	**Cellular response** • AstraZeneca vaccine has been shown to produce cellular immune responses that did not appear to increase after the second dose. • Cellular immune responses do not appear to differ between age groups. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.
Protection against variants, including variants of concern	**B.1.1.7 (identified in UK)** • In countries where B.1.1.7 was the dominant circulating strain (>90% of sequenced samples), estimates of vaccine effectiveness of the Pfizer-BioNTech vaccine were comparable to vaccine efficacy against the parent strain. **B.1.351 (identified in South Africa)** • There is emerging data on the efficacy or effectiveness of mRNA vaccines against B.1.351.	**B.1.1.7 (identified in UK)** • Data suggest AstraZeneca vaccine has a vaccine efficacy against B.1.1.7 that is comparable to that against non-B.1.1.7 disease (74.6% vs. 84.1% respectively) [19]. **B.1.351 (identified in South Africa)** • Data suggest AstraZeneca vaccine has a vaccine efficacy of 10.4% against B.1.351 against mild to moderate illness [20].

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
	P.1 and P.2 (identified in Brazil) • There is limited data on the efficacy or effectiveness of mRNA vaccines against P.1 (variant of concern) and P.2 (variant of interest).	**P.1 and P.2 (identified in Brazil)** • There is limited data on the efficacy or effectiveness of viral vector vaccines against P.1.
Safety	**Technology** • mRNA vaccines use a new technology (which has been studied in experimental vaccines); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.	**Technology** • Viral vector vaccines use a relatively new technology (the authorized Ebola vaccine uses this technology); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.
	Safety Signals • There have been no serious safety signals identified with either mRNA vaccine. Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines. • For both vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events, including fever, are more frequent after the second dose.	**Safety Signals** • Some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events are less frequent after the second dose. For the AstraZeneca vaccine, rare cases of thrombosis and thrombocytopenia have been reported during post-licensure use. The mechanism of action appears to be a spontaneous form of heparin-induced thrombocytopenia (called VITT-Vaccine-Induced Immune Thrombotic Thrombocytopenia). The rate of this adverse event is still to be confirmed but current estimates vary between 1 case per 26,000 and 1 per 500 000 people vaccinated with AstraZeneca vaccine. Case fatality of VITT depends on prompt detection, diagnoses and treatment and is estimated to be between 21 to 60%.
Ethics and Equity	• mRNA vaccines have high short-term efficacy in all authorized age groups and Canada anticipates having enough doses of mRNA vaccines for every individual in Canada in 2021.	• Offering any COVID-19 vaccine to those who would otherwise have to wait to receive one could enhance equity. • If protection against COVID-19 disease cannot be boosted for those that received a lower efficacy vaccine first, significant

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
	• Vaccines that are more efficacious may be directed to those who are most at risk of severe disease and exposure to limit the exacerbation of existing inequities. • The impact of not offering a less efficacious vaccine earlier to populations who would otherwise have to wait to receive an mRNA vaccine in areas with a high risk of transmission and infection, should take into consideration trust, justice, and the risk of doing harm vs good.	inequities could be created for those who receive the AstraZeneca vaccine compared to mRNA vaccines, depending on which population groups received the AstraZeneca vaccine. • The AstraZeneca vaccine may offer an option for individuals who are allergic to mRNA vaccine ingredients or their containers. The impact of offering a less efficacious vaccine earlier to some populations should take into consideration trust, justice and the risk of doing harm vs. good.
Feasibility	**Vaccine schedule** • Both mRNA vaccines are given as a two-dose series. • The mRNA vaccines have an authorized schedule of 21 (for the Pfizer vaccine) or 28 days (for the Moderna vaccine) between dose one and dose two. NACI has recommended an extended interval between the first and second dose of up to 4 months to maximize the number of individuals who can be vaccinated as quickly as possible with available vaccine supplies. This could allow for more individuals to receive one dose of the vaccine and have some protection against symptomatic COVID-19 disease.	**Vaccine schedule** • The AstraZeneca vaccine is given as a two-dose series. The interval between the first and second dose of the AstraZeneca vaccine seems to impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. NACI has recommended an extended interval between the first and second dose of up to 4 months to maximize the number of individuals who can be vaccinated as quickly as possible with available vaccine supplies. • Vaccine recipients need to be advised of the VITT safety signal and the symptoms to watch for after vaccination.
	Storage requirements • The mRNA vaccines have more challenging transport and storage requirements, requiring frozen or ultra-frozen cold chains. Significant efforts have been undertaken to address these logistical complexities. The storage requirements for these vaccines increase the logistical complexity of offering these vaccines in some venues to increase access for various populations.	**Storage requirements** • The AZ vaccine is easier to transport, store and handle than mRNA vaccines, and as a result, could be easier to use for wider distribution via pharmacies and primary healthcare providers. • The AstraZeneca vaccine requires storage and transport at +2 to +8°C, which uses standard cold chain infrastructure widely available in provinces and territories. • The storage requirements for this vaccine could increase access to the vaccine for various populations.
Acceptability	• It is possible that individuals will favor mRNA vaccines since they have higher proven efficacy. • Fewer cases of COVID-19 are expected after vaccination with a vaccine with high efficacy. The relatively low incidence of cases	• It is possible that individuals will favor the AstraZeneca vaccine if it offers an earlier opportunity to receive a COVID-19 vaccine and is more convenient to access if it is available at more convenient locations due to ease of transport, storage and handling.

Contient des renseignements non classifiés

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccine**
	post-vaccination could positively affect acceptability of COVID-19 vaccines and vaccines in general.	• A greater number of COVID-19 cases are expected after vaccination with a vaccine that has lower efficacy. The relatively higher incidence of cases post-vaccination could negatively affect the public's acceptability of COVID-19 vaccines and vaccines in general. • Recent cases of VITT detected after administration with AstraZeneca vaccine may impact its acceptability.

	Concerns about vaccine safety and effectiveness are the two most cited reasons for vaccine refusal [21]
	• In a survey of Canadians conducted between February 9 and 16, 2021 [22], the following results were reported:
	  ○ Of those who indicated they have not yet been vaccinated (n=1954), more respondents 'Agreed' or 'Strongly Agreed' with items stating intention to get a 'safe vaccine' (69%) and an 'effective vaccine' (67%) since Wave 4 (late May-early June).
	  ○ When respondents who were willing or neutral towards getting vaccinated were asked what is most important with respect to selecting a COVID-19 vaccine to receive (n=1595), 46% selected "Receiving the most effective vaccine", 15% selected "Receiving any vaccine as soon as possible" and 12% selected "Receiving the vaccine with the fewest reported side effects". The number of doses and type of vaccine technology were not important factors, and 14% of respondents indicated they have no preference on what COVID-19 vaccine they receive.
	  ○ For those who will wait to get the vaccine once it is available: 80% will wait to ensure the safety of the vaccine, 64% will wait to ensure the effectiveness of the vaccine (n=691) [23]
	• In a survey of health care providers conducted on Dec 4-13, 2020 [24], the most important factors reported to influence the decision to receive vaccine were vaccine safety (95.5%), followed by vaccine effectiveness (86.7%) (n=14,336)	

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VI. RESEARCH PRIORITIES

COVID-19 disease and associated vaccines are novel; therefore, research is warranted in many areas. Research to address the following outstanding questions (not ordered in terms of importance) is encouraged, drawing from both short-term and long-term data, where available:

New and Emerging Research Priorities

Efficacy, Effectiveness, Immunogenicity and Safety

1. What is the population effectiveness (against infection/transmission, hospitalization and death) and medium and long-term duration of protection of a single dose or a complete series of each COVID-19 vaccine approved in Canada?
2. What is the efficacy, effectiveness, immunogenicity, and safety of COVID-19 vaccines across diverse population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children/adolescents, frailty)?
3. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines in individuals who have had a previous laboratory evidence of SARS-CoV-2 infection?
    a. Is there a discernable difference between seronegative and seropositive people in any of the above parameters?
    b. Does previous exposure to SARS-COV-2 impact efficacy, effectiveness, immunogenicity or safety of COVID-19 vaccines?
    c. Can a single-dose vaccine series be as effective and safe in individuals with previously proven COVID-19 disease?
    d. Are there any emerging safety signals with COVID-19 immunization that are not predicted by the current understanding of the safety profile of similar vaccines?
    e. Does vaccination following prior SARS-CoV-2 infection or vaccination of SARS-CoV-2 naïve individuals elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 or other endemic coronaviruses?
4. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines (including potential boosters) against SARS-CoV-2 VOC?
5. What is the correlate of protection for SARS-CoV-2? How are immune responses induced by natural infection similar or different from those induced by vaccines against COVID-19? Is SARS-CoV-2 natural infection (symptomatic or asymptomatic) associated with protection against re-infection or severe disease?
6. Further immunological evidence is needed in the following areas to inform efficacy predictions:
    a. How do immune responses change over time; what is the durability of immune responses against SARS-COV-2 over the long-term? What is the impact of vaccine dose or interval on durability?

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   b. Which immune responses are most important for protection from infection (adaptive or innate immunity), severe disease or transmissibility? What is the role of humoral vs. cellular immunity in preventing immune escape of viral variants?
   c. Are immunoglobulin (Ig)A/IgG/IgM antibodies protective against SARS-CoV-2 and what is the correlate of protection?

7. What level of COVID-19 vaccination coverage is required to achieve various public health milestones, including: coverage to reduce the burden on the health care system to a manageable degree, achieve herd immunity to protect non-vaccinated individuals, and remove PHM controls. What vaccine characteristics play the largest role on these milestones (i.e., efficacy, durability, uptake)?
8. What is the background level of Canadian vaccine-vector-specific responses (i.e., anti-Chimpanzee adenovirus)? Are these responses higher in some groups? Will these responses interfere with vaccine efficacy of these highly seropositive groups? What is the duration of anti-vector interference immunity following viral vector vaccines?
9. How will viral variants impact the efficacy, effectiveness, immunogenicity and safety of a vaccine with respect to death, severe disease, symptomatic disease, asymptomatic disease, infectivity and transmission? What is the effect of using booster vaccines containing heterologous antigens and what is the optimal timing for booster vaccination?
10. Are any components of the COVID-19 vaccine at high risk of inducing an anaphylactic reaction?
11. What is the incidence of rare, serious adverse events following immunization with COVID-19 vaccines?
    a. What is the incidence of thrombosis and thrombocytopenia including CVST and DIC after COVID-19 immunization? What is the trigger for the development of this adverse event following immunization and what can be done to mitigate its development?
12. Does endemic coronavirus infection history impact the course of SARS-CoV-2 disease? Is there cross-protection or interference from antibodies/exposure to human seasonal coronaviruses when exposed to SARS-CoV-2 or vaccinated against SARS-CoV-2?
13. Are there any negative interactions between COVID-19 vaccination and other medications? What is the recommended timing between COVID-19 vaccines and anti-SARS-CoV-2 prophylactic or therapeutic antibodies or convalescent plasma?
14. Does vaccination have an impact on the transmissibility of SARS-CoV-2 in individuals with asymptomatic infection?
15. What is the role of seasonal attenuation of SARS-CoV-2?
16. How does vaccination impact individual-level variation in transmission (e.g., superspreaders)?
17. What is the epidemiology of SARS-CoV-2 VOC over time and across the country and its regions? What are the transmissibility and virulence (including hospitalizations and deaths) of the VOC?

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18. What are the epidemiological characteristics of breakthrough illness (e.g., vaccine recipient characteristics, SARS-CoV-2 VOC)?

Vaccine Administration

19. Are any COVID-19 vaccines interchangeable to complete a regular vaccine series? What is the efficacy, effectiveness, immunogenicity and safety of a mixed dose schedule or a mixed dose booster series?
20. What are the minimum, maximum and optimal intervals between doses of a two-dose COVID-19 vaccine schedule that continue to provide protection against disease?
21. Are any other vaccines (e.g., Bacillus Calmette-Guérin) protective against COVID-19 through off-target effects?
22. Can COVID-19 vaccine be simultaneously administered with other, non-COVID-19 vaccines (either live or inactivated vaccines)? If not, what is the minimum interval between administrations?
23. Can COVID-19 vaccines be given in individuals who have received convalescent plasma or anti-SARS-CoV-2 spike protein monoclonal antibodies? If so, what is the minimum interval required for vaccine administration following receipt of convalescent plasma or monoclonal antibodies?

Standing Research Priorities

COVID-19 infection and disease

1. What is the epidemiological profile of COVID-19 (e.g., communicable period, all risk groups)?
    a. What is the disease distribution and spectrum of clinical illness for COVID-19, including burden of illness and risk by age, sex and other demographic variables associated with higher risk?
    b. What are the transmission dynamics of COVID-19, including degree of asymptomatic transmission, role of children in transmission, vertical transmissibility, onset and duration of viral shedding and communicable period, impact of changing weather conditions, and trends over time?
    c. What are the rates of COVID-19 co-infections with other respiratory pathogens and what is the impact on pathogenesis and clinical outcomes?
2. Can COVID-19 vaccine be used to protect household contacts of a case from infection? Does COVID-19 vaccination decrease infectiousness and clinical illness in individuals that have already acquired infection? Is COVID-19 vaccination effective in interrupting transmission?

Ethics, Equity, Feasibility and Acceptability

3. What is the acceptability of (a) publicly funded COVID-19 vaccines and (b) other vaccines over time and over different epidemiological contexts among key populations, marginalized populations, providers and policy-makers in different epidemiological contexts across the country?

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a. What factors affect acceptability of immunization with a COVID-19 vaccine in these groups?
b. What factors affect acceptability of immunization in general?
c. How will acceptability of prioritized key populations for early immunization with COVID-19 vaccines evolve in different epidemiological contexts across the country?
d. What strategies can improve acceptability of a COVID-19 vaccine in these groups?

4. How can vaccine allocation decisions be communicated to individuals and communities in order to maintain trust in public health authorities?

5. What COVID-19 vaccination strategies or implementation strategies can reduce health inequities in populations directly targeted by vaccination and in populations not directly targeted by immunization?

6. Can a different COVID-19 vaccine be used to complete a primary series or as a booster dose? How are returning travellers managed if they have initiated but not completed a COVID-19 vaccine series abroad?

Health-Related Quality of Life and Well-being

7. What is the health-related quality of life or well-being of COVID-19 patients and caregivers over time (e.g., health utilities, patient-reported outcomes, patient-reported experiences measures)?

8. What is the impact of COVID-19 vaccination on health-related quality of life or well-being on individuals?

VII. SURVEILLANCE ISSUES

Ongoing and systematic data collection, analysis, interpretation and timely dissemination is fundamental to planning, implementation, evaluation, and evidence-informed decision-making. To support such efforts, NACI encourages surveillance improvements in the following areas:

1. Epidemiology

- Enhance social and socioeconomic data collected and made available to understand and address health inequities related to COVID-19
- Systematic examination of the Canadian burden and epidemiology of COVID-19 outbreaks by setting and severity, identifying high-risk activities, settings and populations
- Evaluation of the success of public health interventions to minimize or prevent COVID-19 outbreak events, especially in vulnerable or high-risk communities

2. Laboratory (e.g., strain characterization)

- Enhance laboratory surveillance in order to provide early warning of increasing or decreasing activity by age, sex, and presence of symptoms, and help interpret case data based on changes to testing algorithms

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- Conduct genomic surveillance to identify international and inter-provincial transmission and new strains/variants with differing severity, transmissibility, or vaccine comparability
- Explore other SARS-CoV-2 detection kits at point of care with immediate results.

3. Vaccine (coverage, effectiveness, safety)

- Reliably monitor coverage rates for each authorized COVID-19 vaccine in different key populations, ensuring data on series completion
- Ensure existing mechanisms for the evaluation of adverse events are positioned to generate data for each authorized COVID-19 vaccine

TABLES

Table 6. Strength of NACI Recommendations

Strength of NACI Recommendation *based on factors not isolated to strength of evidence* (e.g., public health need)	**STRONG**	**DISCRETIONARY**
Wording	"*should/should not be* offered"	"*may/may not be* offered"
Rationale	Known/anticipated advantages outweigh known/anticipated disadvantages ("should"), OR Known/Anticipated disadvantages outweigh known/anticipated advantages ("should not")	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists
Implication	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may/may not be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

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LIST OF ABBREVIATIONS

Abbreviation	*Term*
AE	Adverse event
AEFI	Adverse event following immunization
ARCHE	Alberta Research Center for Health Evidence
CDC	Centres for Disease Control and Prevention (United States)
ChAd	Chimpanzee Adenovirus
CI	Confidence interval
CIC	Canadian Immunization Committee
CIG	Canadian Immunization Guide
COVID-19	Coronavirus disease 2019
CVST	Cerebral venous sinus thrombosis
DART	Developmental and Reproductive Toxicity
DIC	Disseminated intravascular coagulation
EEFA	Ethics, Equity, Feasibility, and Acceptability
EMA	European Medicines Agency
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	Human immunodeficiency virus
IM	Intramuscular
Ig	Immunoglobulin
IGRA	Interferon gamma release assay
JCVI	Joint Committee on Vaccination and Immunisation (UK)
MAAE	Medically attended adverse event
MenACWY	Quadrivalent meningococcal vaccine
mRNA	messenger ribonucleic acid
NACI	National Advisory Committee on Immunization
NITAG	National Immunization Technical Advisory Group
PCR	Polymerase chain reaction
PHAC	Public Health Agency of Canada
SAE	Serious adverse events
SAGE	Strategic Advisory Group of Experts on Immunization (WHO)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SD	Standard dose
SII	Serum Institute of India
SOC	System organ class

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TST	Tuberculin skin test
UK	United Kingdom
US	United States
VIPIT	Vaccine-Induced Prothrombotic Immune Thrombocytopenia
VITT	Vaccine-Induced Thrombotic Thrombocytopenia
VOC	Variants of concern
VPD	Vaccine preventable disease
WHO	World Health Organization

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ACKNOWLEDGMENTS

This statement was prepared by: SJ Ismail, K Young, MC Tunis, A Killikelly, R Stirling, O Baclic, J Zafack, M Salvadori, N Forbes, L Coward, C Jensen, R Krishnan, Y-E Chung, B Warshawsky, E Wong, K Farrah, S Deeks, and C Quach on behalf of the High Consequence Infectious Disease Working Group (HCID WG) and was approved by NACI.

NACI gratefully acknowledges the contribution of: C Mauviel, K Ramotar, V Ferrante, S Pierre, E Tice, A Sinilaite, MW Yeung, L Whitmore, J Shurgold, J Vachon, J Macri, J Mielczarek, R Goddard, B Sader, M Patel, A House, and A Nam, the Alberta Research Centre for Health Evidence, and the PHAC Public Health Ethics Consultative Group.

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APPENDIX A: EVIDENCE SUMMARY FOR PFIZER-BIONTECH COVID-19 VACCINE

Study C4591001 is the pivotal Phase 1/2/3 trial for the Pfizer-BioNTech COVID-19 vaccine. Evidence on immunogenicity is available for adults 18 to 55 and 65 to 85 years of age. Evidence on the safety and efficacy of the vaccine is available for adults 16 years of age and older. Studies did not include participants from long term care facilities. The Phase 2/3 portion of the trial involved approximately 44,000 study participants randomized (1:1) to receive either the vaccine or placebo. The data presented below are for an interim analysis, therefore the time of follow-up is not consistent but was less than four months after the second dose (maximum of 14 weeks) for all participants.

Evidence from the ongoing Phase 2/3 trial were published recently, after NACI's review of the evidence [25].

Efficacy

Severe outcomes due to COVID-19

There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death [26].

There may be a protective effect against severe COVID-19 outcomes when receiving at least one dose of vaccine (overall vaccine efficacy of 88.9%, 95% CI: 20.1 to 99.7%), based on one case identified in the vaccine group (N=21,669) and nine cases in the placebo group (N=21,686). Vaccine efficacy against severe COVID-19 disease was also examined after receipt of Dose 2 (from 7 days and 14 days after Dose 2), but there were an insufficient number of events reported (one severe outcome in the vaccine group and three in the placebo group for each outcome) to determine whether the vaccine was efficacious in reducing severe outcomes with any precision (i.e., the resulting point estimates had wide confidence intervals that included zero).

Symptomatic COVID-19 disease

The estimated vaccine efficacy at least 7 days after Dose 2 was 94.6% (95% CI: 89.9 to 97.3%), with 9 confirmed symptomatic COVID-19 cases, as defined in trial protocol [25] identified among vaccine recipients (N=19,965) compared to 169 cases among placebo recipients (N=20,172). The vaccine efficacy at least 14 days after Dose 2 in this population was comparable (94.4%, 95% CI: 89.1 to 97.3%). Results were similar when estimating the efficacy specifically in individuals without evidence of prior SARS-CoV-2 infection at 95.0% (95% CI: 90.3 to 97.6%) with 8 confirmed cases among vaccine recipients (N=18,198) compared to 162 cases among placebo recipients (N=18,325).

When study participants without evidence of prior SARS-CoV-2 infection were stratified by age, vaccine efficacy against COVID-19 from 7 days after Dose 2 was between 93.7% (>55 years) and 95.6% (16 to 55 years). In individuals ≥65 years of age, vaccine efficacy was 94.7% (95% CI: 66.7 to 99.9%), while in participants ≥75 years of age, the observed vaccine efficacy was 100% compared to placebo, but with a wide confidence interval including zero which resulted

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from an insufficient number of events reported (0 vs 5 cases, 95% CI: –13.1 to 100.0%). The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 91% (between 91.7% and 100.0%) in all subgroups stratified by "at risk" status (e.g., presence of a 1 or more comorbidities). The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 89% for all races (89.3 to 100%) and 94% for all ethnicities included in the sub-analysis (94.4 to 95.4%).

After Dose 1, but prior to administration of Dose 2, 39 COVID-19 cases were identified in the vaccine group (n=21,669) compared to 82 in the placebo group (n=21,686) for an overall estimated vaccine efficacy of 52.4% (95% CI: 29.5 to 68.4%). If the analysis was restricted to cases identified only in the time period >14 days after dose 1 to before dose 2 the estimated vaccine efficacy increased to 92.3% (95% CI: 69 to 98%).

Table 7. Pfizer-BioNTech vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1[a]

Time period of interest	Events in vaccine group (N=21,669)	Events in placebo group (N=21,686)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1 to before dose 2	39	82	52.4% (29.5 to 68.4%)
>14 days after dose 1 to before dose 2[b]	2	27	92.3% (69 to 98%)

[a] In the all-available efficacy population consisting of randomized study participants who received at least one dose of the study intervention (i.e., vaccine or placebo)

[b] Comité sur l'immunisation du Québec. Stratégie de vaccination contre la COVID-19 : report de la 2e dose en contexte de pénurie. Institut national de Santé Publique du Québec, 18 décembre 2020

There is no analysis provided for efficacy specifically in individuals with prior evidence of SARS-CoV-2 infection.

Asymptomatic infection and transmission
There are no efficacy data for these outcomes at this time.

Immunogenicity

Humoral immune responses
Both SARS-CoV-2 binding and neutralizing antibodies induced by this vaccine had similar trends across both age groups studied (N=195). Maximal immune responses were seen on day 28, 7 days after the second dose. Binding and neutralizing antibodies were both induced by one dose of vaccine and boosted by the second dose of vaccine. The immune response elicited by one dose accounted for 10-20% of the maximal immune response. Up to day 35, older adults (65-85 years of age) had a lower immune response compared to younger adults (18-55 years of age). After the peak on day 28, immune responses decreased until the final evaluation point on day 52, 30 days after dose 2 in younger adults, while no decrease was observed in older adults. At all time points and age groups, immune responses were higher than placebo.

Cellular immune responses
Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine, as demonstrated by the increase in these cell population percentages from day 1 to day 28. Increases were seen in both younger adults (18-55 years of age) and older adults (65-85 years

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of age). The characterization of these cells indicates a Th-1 biased cellular immune response. Intermediate time points were not reported.

Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 37,586 participants with a median of two months of follow-up (range: <2 weeks to <14 weeks) after Dose 2. About 19,000 participants had at least 2 months of follow-up, including about 9,500 who received the vaccine. Participants who inadvertently received the vaccine (n=12) or placebo (n=11) while pregnant are being followed.

Local Reactions

In vaccine recipients, frequency of local reactions was similar after Dose 1 and Dose 2. Pain at the injection site was very common (occurred in 66.1 to 83.1%, dependent on age and whether it was Dose 1 or Dose 2 administered). Most local reactions among vaccine recipients were mild or moderate in severity, with any severe reactions being reported by ≤0.6% of participants. No Grade 4 local reactions were reported. Across both age groups, local reactions after either dose had a median onset between zero and 2 days post-vaccination and a median duration of 1 to 2 days.

Systemic Reactions

Systemic events were generally increased in frequency and severity in vaccine recipients compared to placebo recipients, and in the younger age group (16-55 years old) compared with the older age group (≥56 years old), with frequencies and severity increasing with the number of doses (Dose 2 compared to Dose 1). Fatigue (34.1 to 59.4%), headache (25.2 to 51.7%), and muscle pain (13.9 to 37.3%) were very common in all age groups and after Dose 1 and Dose 2, respectively. Fever was common after the first dose (3.7% of 16-55 year olds, 1.4% of >55 year olds) but was very common after the second dose (15.8% of 16-55 year olds, 10.9% of >55 year olds). Joint pain was very common or common in all age groups (11.0 to 21.9% of 16-55 year olds, 8.6 to 18.9% of >55 year olds). Diarrhea was very common or common in both age groups (10.0 to 11.0% of 16-55 year olds, 8.0% of >55 year olds), but was similar to rates seen in the placebo group and did not appear to differ between Dose 1 and Dose 2.

Across age groups, the median onset day for most systemic events after either dose of vaccine was 1 to 2 days post-vaccination, with a median duration of 1 day. The majority of systemic events were mild or moderate in severity.

Overall, the frequency of any severe systemic event after Dose 1 was ≤0.9%. After Dose 2, severe systemic events had frequencies of <2% with the exception of fatigue (3.8%) and headache (2.0%). The proportion of participants that experience severe fever (>38.9°C to 40.0°C) increased between Dose 1 (0.2%) and Dose 2 (0.8%). Grade 4 fever (>40.0°C) was reported for 2 participants in each of the vaccine and placebo groups.

Severe or Serious Adverse Events

In total, 1.1% and 0.1% of participants in the vaccine group experienced at least one severe AE and one life-threatening adverse events (AE), respectively, compared to 0.7% and 0.1% of participants in the placebo group. There were no clinically meaningful differences in AEs by category observed by age, sex, or race/ethnicity.

The proportions of participants who reported at least 1 serious adverse event (SAE) were similar in the vaccine group (0.5%) and in the placebo group (0.4%). Three of the SAEs in the vaccine group and none in the placebo group were assessed by the investigator as related to study

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intervention: 1 SAE each of shoulder injury related to vaccine administration, ventricular arrhythmia, and lymphadenopathy. No clinically meaningful differences in SAEs were observed by age, sex, or race/ethnicity. After either vaccine dose, no participant reported an immediate allergic reaction to vaccine.

Other serious adverse events

Lymphadenopathy

Lymphadenopathy was not a solicited AE. Among participants (n=37,586) who were followed for <2 weeks to <14 weeks after Dose 2, AEs of lymphadenopathy were reported in 0.3% (n=64) participants (0.5% [n=54] in the younger age group and 0.1% [n=10] in the older age group) in the vaccine group and 6 participants (0.0%) in the placebo group. Among the AEs of lymphadenopathy in the vaccine group, the majority (47 of 64) were judged by the investigator as related to the vaccine. Most lymphadenopathy events were reported within 2 to 4 days after vaccination. The average duration of these events was approximately 10 days, with 11 events ongoing at the time of the data cut-off.

Appendicitis

Among participants who were followed <2 weeks to <14 weeks after Dose 2, there were a total of 12 participants with SAEs of appendicitis; 8 of which were in the vaccine group. Six of those 8 occurred in younger adults and 2 occurred in older adults. None of the cases were assessed as related to the vaccine by the investigators. The rate in either age group was not estimated to be greater than expected compared to baseline rates.

Death

There were 6 participants who died as of 14 November 2020, the data cut-off date for the interim analysis. This included 2 participants in the vaccine group and 4 participants in the placebo group. None of these deaths in the vaccinated group were assessed by the investigator as related to the vaccine.

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APPENDIX B: EVIDENCE SUMMARY FOR MODERNA COVID-19 VACCINE

Pivotal Phase 1, 2, and 3 trials are being conducted for the Moderna COVID-19 vaccine. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. Studies did not include participants from long term care facilities. The Phase 3 portion of the trial involved 30,413 study participants randomized (1:1) to receive either the vaccine (2 doses of 100 mcg) or placebo. The data presented below are for an interim analysis, therefore the time of follow-up is not consistent but was a median of two months after the second dose (maximum of 14 weeks) for all participants.

Efficacy

Severe outcomes due to COVID-19
There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, as defined in the trial protocol [27]

The efficacy of the Moderna COVID-19 vaccine to protect against severe COVID-19 cases occurring at least 14 days after the second injection was in 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group). There were 30 confirmed severe COVID-19 cases in the placebo group compared to 0 cases in mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%).

Symptomatic COVID-19 disease
The primary efficacy outcome examined the efficacy of Moderna COVID-19 vaccine to protect against confirmed symptomatic COVID-19 starting 14 days after Dose 2 in study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline. This analysis included 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group), with a median time of follow-up after receiving the second injection of 63 days. There were 185 confirmed COVID-19 cases [28] occurring at least 14 days after the second injection among placebo recipients compared to 11 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.1% (95% confidence interval, CI: 89.3 to 96.8%).

A subgroup analysis of the interim primary efficacy outcome was conducted in three age groups: 18 to <65 years of age (10,521 participants in the placebo group and 10,551 participants in the Moderna COVID-19 vaccine group), ≥65 years of age (3,552 participants in the placebo group and 3,583 participants in the Moderna COVID-19 vaccine group), and a further subgroup of study participants ≥75 years of age (688 participants in the placebo group and 630 participants in the Moderna COVID-19 vaccine group).

In study participants 18 to <65 years, there were 156 confirmed COVID-19 cases occurring at least 14 days after the second injection among placebo recipients compared to 7 cases among mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 95.6% (95% CI: 90.6 to 97.9%). The corresponding incidence rate per 1,000 person-years (total time at risk in each treatment group) was 64.63 in the placebo group and 2.88 in the Moderna COVID-19 vaccine group. In study participants ≥65 years of age there were 29 confirmed COVID-19 cases among

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placebo recipients compared to 4 cases among Moderna COVID-19 vaccine recipients, corresponding to a somewhat lower point estimate of vaccine efficacy of 86.4% (95% CI: 61.4 to 95.2%). The corresponding incidence rate per 1,000 person-years was 33.73 in the placebo group and 4.60 in the Moderna COVID-19 vaccine group. In the subgroup of study participants ≥75 years of age there were 7 confirmed COVID-19 cases among placebo recipients compared to 0 cases among Moderna COVID-19 vaccine recipients, for a corresponding vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%), but this must be interpreted with caution as there were few events identified in this age group.

The efficacy of the Moderna COVID-19 vaccine to protect against confirmed COVID-19 cases occurring at least 14 days after the second injection was also assessed in participants most at risk for severe complications of COVID-19. In study participants 18 to <65 years of age and at risk for severe complications of COVID-19 (2,118 participants in the placebo group and 2,155 participants in the Moderna COVID-19 vaccine group) there were 35 confirmed COVID-19 cases in the placebo group compared to 2 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.4% (95% CI: 76.9 to 98.7%). In study participants 18 to <65 years of age, but not at risk for severe complications of COVID-19 (8,403 participants in the placebo group and 8,396 participants in the Moderna COVID-19 vaccine group) the estimated vaccine efficacy was 95.9% (95% CI: 90.0 to 98.3%) based on 121 confirmed COVID-19 cases in the placebo group and 5 cases among Moderna COVID-19 vaccine recipients. Vaccine efficacy estimates were also calculated for select individual co-morbid conditions; however, as of November 7, 2020 the number of identified events in these subgroups (n=0 to 11) were too small for meaningful analysis

A secondary analysis of vaccine efficacy to protect against the first occurrence of confirmed COVID-19 starting 14 days after Dose 2 regardless of prior SARS-CoV-2 infection, as determined by serologic titre, involved the full analysis set (randomly assigned study participants who received at least one injection). There were 30,351 study participants 18 years of age or older (15,170 participants in the placebo group and 15,181 participants in the Moderna COVID-19 vaccine group). There were 187 confirmed COVID-19 cases among placebo recipients compared to 12 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 93.6% (95% CI: 88.6 to 96.5%). However, there was a small proportion of study participants enrolled (n=679/29,148; 2.3%) with positive SARS-CoV-2 infection status at baseline.

In participants who had only received one dose of vaccine at the time of data analysis (placebo group: n=1,079; vaccine group: n=996), vaccine efficacy was 80.2% (95% CI: 55.2 to 92.5%). Limiting the analysis to 14 or more days after Dose 1, efficacy rose to 92.1% (95% CI: 68.8 to 99.1%). However, there are limited data on the efficacy of Dose 1 alone beyond 28 days post-vaccination.

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Table 8. Moderna vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1[a]

Time period of interest	Events in vaccine group (N=996)	Events in placebo group (N=1,079)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1	7	39	80.2% (55.2 to 92.5%)
>14 days after dose 1	2	28	92.1% (68.8 to 99.1%)

[a] In the modified intention-to-treat population consisting of randomized study participants who had received only one dose of their assigned intervention (i.e., vaccine or placebo) at the time of analysis

Asymptomatic infection and transmission

Nasopharyngeal swabs for SARS-CoV-2 virus were collected for all participants at specified intervals before Dose 1 and before Dose 2. There were 14 participants in the vaccine arm who were previously seronegative before administration of Dose 1 who had asymptomatic infection at the second time point, compared to 38 participants in the placebo arm. No formal efficacy data are available; however, assessment of this outcome is ongoing.

Immunogenicity

Humoral immune responses

Antibodies that bind the spike protein were induced in vaccine recipients by day 15 (15 days after dose 1) and reach maximum levels on day 43 (15 days after dose 2). Maximal binding antibody responses approximate the levels of the highest affinity samples of convalescent sera. Binding antibodies reached elevated levels on day 36 (7 days after dose 2) and persisted but decreased through day 119 (90 days after dose 2), the last day for which data is available.

Binding antibodies induced by 1 dose of the vaccine (i.e., on day 29) were 10-20% of the elevated responses seen on day 36. It is unknown how binding antibody responses change over time. Binding antibody responses through day 36 seems to be approximately equivalent across age groups. The data may suggest an age-dependent binding antibody durability. Antibody responses for age 70 or below decreased more slowly than for those above 70.

Neutralizing antibodies weren't induced to the level of convalescent sera until day 36, 7 days after dose 2 for all age groups. Neutralizing antibody responses through day 36 seems to be approximately equivalent across age groups. Neutralizing antibody responses on Day 119 represent a larger proportion of the maximum on day 43, compared to binding antibody responses. This may indicate increased durability of neutralizing antibody responses compared to binding antibody responses. These neutralizing data may also suggest an age-dependent neutralizing antibody durability as antibody responses on day 119 for each cohort were inversely proportional to the age of the cohort.

Cellular immune responses

Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine. Maximal induction of both CD4+ and CD8+ T cells was observed on day 43, 14 days after dose 2. The percentage of CD8+T cells was lower for all age groups compared to CD4+ T cells. By comparing the percentage of cells that express Th-1 (IFN gamma, IL-2, TNF) vs. Th-2 (IL-4 and IL-13), it was demonstrated that this vaccine induces a Th1-biased cellular immune response.

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Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 30,351 participants with a median follow-up time of 63 days after Dose 2 (92 days after Dose 1). 23,276 participants had at least one month of follow-up after Dose 2 (12,021 individuals received the vaccine) and 7,667 individuals had at least 2 months of follow-up after Dose 2 (3894 individuals received the vaccine) [28]. Participants who inadvertently received the vaccine (n=6) or placebo (n=7) while pregnant are being followed.

Solicited Local Reactions

In vaccine recipients, frequency of local reactions increased from Dose 1 to Dose 2. Pain at the injection site was very common (occurred in 83.7% of vaccine recipients after Dose 1 and in 88.2% of vaccine recipients after Dose 2). Redness was common (2.8 to 8.6%) and swelling was common to very common (6.1 to 12.2%). Grade 3 (severe) reactions were reported by 3.5% and 7.0% of vaccine recipients after Dose 1 and Dose 2, respectively [28]. No Grade 4 local reactions were reported. The majority of local reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 3 days. Delayed injection-site reactions (i.e. with onset on day 8 or after) were noted in 0.8% of participants after the first dose and in 0.2% of participants after the second dose. Reactions were characterized by erythema, induration, and tenderness, and they resolved within 4 to 5 days.

Localized axillary swelling and tenderness was solicited and occurred in less than 5% of placebo recipients after any dose, and 10.2% and 14.2% of vaccine recipients after Dose 1 and 2, respectively. Among vaccine recipients, the incidence of severe (Grade 3) axillary swelling and tenderness increased from Dose 1 to Dose 2 (0.3 to 0.5%), whereas in the placebo group it decreased from Dose 1 to Dose 2 (0.2 to 0.1%) [28].

Solicited Systemic Reactions

Systemic events generally had a higher frequency and severity in vaccine recipients compared to placebo recipients, with frequency and severity increasing with the number of doses (Dose 1 compared to Dose 2). In vaccine recipients, fatigue (37.2 to 65.3%), headache (32.6 to 58.6%), muscle pain (22.7 to 58.0%), and arthralgia (16.6 to 42.8%) were very common in all age groups and after Dose 1 and Dose 2, respectively. Chills and nausea/vomiting were very common or common (8.3 to 44.2% and 8.3 to 19.0%, respectively). Fever was uncommon after the first dose (0.8%) but was very common after the second dose (15.5%).

Grade 3 reactions were reported by 2.9% and 15.7% of vaccine recipients after Dose 1 and Dose 2, respectively [28]. After Dose 2, Grade 3 fever (1.3%), headache (4.3%), fatigue (9.4%), myalgia (8.7%), arthralgia (5.1%), and chills (1.3%) were common. The proportion of vaccine recipients that experience Grade 3 fever (>38.9°C to 40.0°C) increased between Dose 1 (<0.1%; n=11) and Dose 2 (1.3%; n=202). Among placebo recipients only 2.7% reported Grade 3 adverse events after either dose.

The incidence of any Grade 4 events was <0.1% after both doses in both vaccine (6 to 12 events) and placebo (2 to 4 events) recipients. Grade 4 fever (>40.0°C) was reported for 4 placebo recipients and 4 vaccine recipients after Dose 1, and 2 placebo recipients and 12

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vaccine recipients after Dose 2. The majority of systemic reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 2 days.

Unsolicited Severe or Serious Adverse Events

During the first 28 days after any dose, 1.5% and 0.5% of participants in the vaccine group (Dose 1 and Dose 2, respectively) reported unsolicited severe and serious AEs (SAEs), compared to 1.3% and 0.6% of participants in the placebo group. There was no apparent effect of age on the relative incidence of SAEs in the vaccinated or placebo group.

Three SAEs in vaccinated individuals were considered by the study sponsor to be related to the trial intervention: two cases of facial swelling and one case of nausea and vomiting with headaches and fever.

Four additional SAEs in vaccine recipients and five SAEs in placebo recipients were considered to be related to the trial intervention by trial investigators [28]. Of the SAEs considered related to the Moderna vaccine, 2 cases of autoimmune diseases were reported: one rheumatoid arthritis in a participant known with hypothyroidism, that was unresolved at the time of the report and one autonomic dysfunction in a participant known with hypothyroidism, also unresolved at the time of the report. In the placebo group, one participant (known to have chronic back pain) developed polymyalgia rheumatica, which was resolving.

No clinically meaningful differences in SAEs were observed by age. Sex and race/ethnicity were not assessed. After either vaccine dose, no participant in the Phase 3 study reported an immediate allergic reaction to vaccine.

Other serious adverse events

Facial swelling

Two female participants with a history of dermal filler injection in the cheeks experienced facial swelling 1 to 2 days following immunization. Both were treated and the swelling resolved after a duration of about 5 days. A third female participant with a history of dermal filler injection in the lips had lip angioedema 2 days after vaccination which was classified as medically significant but not considered as an SAE. The management and duration of this third event were not specified.

Death

A total of 13 deaths were reported, 6 in the vaccine group and 7 in the placebo group. None of these deaths were assessed to be related to any study intervention or COVID-19.

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APPENDIX C: EVIDENCE SUMMARY FOR ASTRAZENECA COVID-19 VACCINE

Results from four clinical trials (two Phase 1/2, one Phase 2/3, and one Phase 3) were available at time of authorization for the AstraZeneca COVID-19 vaccine. Results from an ongoing Phase 3 trial in the United States (US) are not available at time of writing. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. The Phase 2/3 trial (COV002) trial and Phase 3 trial (COV003) assessed efficacy, safety and immunogenicity of the vaccine. The Phase 2/3 trial was based in the United Kingdom, (UK) while the Phase 3 trial was based in Brazil. These two studies underwent a series of protocol amendments and logistical challenges during the conduct of the trials that resulted in significant changes to the trials' methodology. There were changes from a single to a two-dose vaccine regimen, the use of both a low dose/standard dose (LD/SD) (in COV002 only, due to dosing error) and standard dose/standard dose (SD/SD) vaccine regimen, and the recruitment of progressively older study participants (56–69 and then ≥70 years of age) after the initial focus on adults 18–55 years of age. In the SD/SD vaccine regimen, study participants were randomized (1:1) to receive either the AstraZeneca COVID-19 vaccine, AZD1222 (5×10^{10} viral particles per 0.5 mL dose) or control injection. The participants randomized to the control group were administered two doses of quadrivalent meningococcal vaccine (MenACWY) (COV002) or MenACWY for Dose 1 and placebo for Dose 2 (COV003).

There were significant differences in the baseline characteristics of participants in the Phase 2/3 and Phase 3 trials. In addition, the clinical trials prioritized the recruitment of health care professionals and other adults with high potential for exposure to SARS-CoV-2, including health care and social setting workers.

Evidence from the AstraZeneca COVID-19 vaccine trials has been published [29].

Efficacy

The estimates of vaccine efficacy for the AstraZeneca COVID-19 vaccine (AZD1222) come from the Phase 2/3 and Phase 3 trials. As of a data cut-off date of November 4, 2020 the primary analysis population (study participants who received either the LD/SD or SD/SD regimens) for the primary outcome included 11,636 participants seronegative at baseline (5,807 in the vaccine group, 5,829 in the control group). Of this population, 8,895 study participants (4,440 vaccine recipients and 4,455 controls) received the SD/SD regimen. As of a data cut-off date of December 7, 2020, the SD/SD population had increased to include 12,158 study participants (6,085 vaccine recipients and 6,073 controls). Unless otherwise noted, all data presented in this summary is based on the SD/SD vaccine regimen and as of a data cut-off date of December 7, 2020.

Symptomatic COVID-19 disease

The primary efficacy outcome assessed in the two trials was prevention of the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2, based on assessments of cases by an Adjudication Committee blinded to participant group assignment, and analysed in the combined LD/SD and SD/SD regimen population. Assessment in the subgroup that only received SD/SD was a pre-specified secondary analysis in the clinical trial. Symptomatic COVID-19 was defined as having at least one of the following symptoms (objective fever ≥37.8

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C, cough, shortness of breath, and anosmia or ageusia) AND a swab positive for SARS-CoV-2 by RT-PCR AND confirmed by an Adjudication Committee.

Based on data as of December 7, 2020, there were 12,158 study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline (6,085 vaccine recipients and 6,073 controls) included as part of the SD/SD regimen analysis. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants receiving the SD/SD vaccine regimen was 62.5% (95% CI: 50.7 to 71.4%), based on identification of 71/6,085 (1.2%) cases in vaccine recipients and 186/6,073 (3.1%) in controls. The estimated vaccine efficacy by age was 63.1% (51.1 to 72.1%) in study participants 18-64 years of age and 50.7% (-65.8 to 85.4%) in participants ≥65 years of age. An ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18–55 years of age who received the SD/SD dosing regimen. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 59.3% (95% CI: 25.1 to 77.9%) in this age group. This analysis included study participants with any interval duration between doses.

Symptomatic COVID-19 by interval

As of December 7, 2020, the majority of study participants in the COV002 (UK) and COV003 (Brazil) clinical trials received the two doses of the SD/SD regimen within a 4–8 week (UK: 45.6%, Brazil: 87.2%) or a 9–12-week interval (UK: 34.4%; Brazil: 10.5%). About 1 in 5 study participants in the UK clinical trial (18.9%) received the SD/SD regimen with a >12-week interval between vaccine doses, and in the Brazil trial it was less than 1 in 50 study participants (1.8%). A very small proportion of study participants received the SD/SD regimen with a <4-week interval between doses (UK: 1.0%, Brazil: 0.4%).

An exploratory analysis examined the potential effect of the interval between the administration of the first and second vaccine doses on vaccine efficacy in study participants receiving the SD/SD vaccine regimen. Table 9 summarizes the estimates of vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 by dosing interval. There is a suggestion of an increase in the point estimate of vaccine efficacy with increasing intervals between the first and second dose of vaccine. However, it is important to note that the confidence intervals around these point estimates overlap.

Table 9. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2 in all participants, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks	67/5,473 (1.2)	162/5,422 (3.0)	59.6% (46.4 to 69.6%)
4 – 8 weeks	52/4,188 (1.2)	113/4,098 (2.8)	55.7% (38.5 to 68.1%)
9–12 weeks	15/1,285 (1.2)	49/1,324 (3.7)	69.0% (44.8 to 82.6%)
>12 weeks	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

In a subgroup analysis in study participants who received the SD/SD vaccine regimen, vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 was estimated

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by dosing interval and age group. These ad-hoc subgroup analyses were performed in participants 18-55 years of age from the COV002 (UK) clinical trial and in all study participants who received the SD/SD regimen (from COV002 and COV003), dichotomized into groups 18–64 years and ≥65 years of age.

The ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18-55 years of age who received the SD/SD regimen at an interval of >8 weeks between doses. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 65.6% (95% CI: 24.5 to 84.4%). In the updated dataset as of December 7, 2020, there were 1,375 study participants ≥65 years of age (699 in the vaccine group and 676 in the control group). Efficacy estimates for participants ≥65 years for the overall 4–12-week dosing interval and the 4–8-week interval have wide confidence intervals that include zero. Estimates of vaccine efficacy could not be calculated for participants ≥65 years for the 9–12-week and >12-week dosing intervals due to a lack of older study participants who received the SD/SD regimen during these dosing intervals (Table 10).

Table 10. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after dose 2, by dosing interval and age group (SD/SD seronegative baseline efficacy set[a])

Dosing interval and age group	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks			
18–64 years	63/4,790 (1.2)	156/4,760 (3.0)	60.5% (47.1 to 70.5%)
≥65 years	4/683 (0.6)	6/662 (0.9)	43.2% (-99.3 to 83.8%)
4 – 8 weeks			
18–64 years	48/3,506 (1.4)	107/3,439 (3.1)	56.6% (39.1 to 69.1%)
≥65 years	4/682 (0.6)	6/659 (0.9)	43.4% (-98.5 to 83.9%)
9–12 weeks			
18–64 years	15/1,284 (1.2)	49/1,321 (3.7)	69.0% (44.8 to 82.6%)
≥65 years	0/1 (0)	0/3 (0)	No estimate
>12 weeks			
18–64 years	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)
≥65 years	0/0 (0)	0/0 (0)	No estimate

[a]Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Symptomatic COVID-19 by presence of co-morbidity

Efficacy was also assessed based on the presence of comorbidity, which was defined as the presence of one or more of the following mild to moderate and controlled medical conditions at baseline: cardiovascular disease, respiratory disease, diabetes, or obesity (BMI ≥30 kg/m^2) based on a data cut-off date of November 4, 2020. For this exploratory analysis, included study participants who were SARS-CoV-2 seronegative at baseline and received the SD/SD regimen. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants without comorbidities was 58.0% (95% CI: 25.8 to 76.2%), based on 17/2,825 (0.6%) cases identified in the vaccine group compared to 39/2,774 (1.4%) cases in the control group. The corresponding estimate of vaccine efficacy in study participants with comorbidities was 67.1% (95% CI: 33.2 to 83.8%), based on the identification of 10/1,611 (0.6%) cases in the vaccine group compared to 32/1,670 (1.9%) cases in the control group.

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Symptomatic COVID-19 after one dose

Efficacy at various time points after one dose of AstraZeneca COVID-19 vaccine was assessed as a secondary/exploratory analysis based on data as of the interim analysis cut-off date of November 4, 2020 (Table 11). The analysis involved study participants who were SARS-CoV-2 seronegative at baseline and received SD vaccine as their initial vaccine dose. The median duration of follow-up after Dose 1 was 115 days (range: 41–149 days). Note that approximately 80% of study participants in the vaccine arm received the second dose of the vaccine; therefore, several estimates of vaccine efficacy are not solely due to the one dose of SD vaccine.

Table 11. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning after Dose 1, (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Events in vaccine group (AZD1222)	Events in control group (MenACWY)	Estimate of vaccine efficacy (95% confidence interval)
After Dose 1	92 (N=8,008)	185 (N=8,013)	50.5% (36.5 to 61.5%)
≥22 days after Dose 1	51 (N=6,307)	141 (N=6,297)	64.1% (50.5 to 73.9%).
≥22 after Dose 1 but before Dose 2	15 (N=6,310)	52 (N=6,296)	71.3% (49.0 to 83.8%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Severe outcomes due to COVID-19

Severe COVID-19 disease

Severe COVID-19 disease, defined as study participants who met the confirmed COVID-19 case definition and were assigned a severity score of ≥6 on the World Health Organization Clinical Progression Scale (e.g., clinical severity requiring hospitalization, and may include intubation and mechanical ventilation, and death), was assessed as a secondary analysis of vaccine efficacy. Analysis included study participants who had been followed for ≥15 days since Dose 2, who were seronegative for SARS-CoV-2 at baseline, and received both doses of the SD/SD regimen. As of December 7, 2020, there were 6,085 study participants in the vaccine group and 6,073 participants in the control group. There was 1 case of severe COVID-19 disease identified in a study participant in the control group who received the control intervention within the 4–12-week dosing interval. This participant also required ICU admission and eventually died. An additional severe case occurred >21 days after the first dose and ≤14 days after the second dose in a study participant in the control group.

Hospitalizations

Vaccine efficacy against COVID-19 associated hospitalizations was assessed at multiple time points (Table 12). Assessment included study participants who were seronegative for SARS-CoV-2 at baseline and received both doses of the SD/SD regimen. After Dose 2 (median follow-up duration: 36 days, range: 1–79 days, based on data as of November 4, 2020), there were 7 hospitalizations due to COVID-19 identified in study participants who received the SD/SD regimen within the 4–12-week dosing interval, all in participants in the control group. There were no hospitalizations in the vaccine group ≥22 days after Dose 1; however, there were 2 cases hospitalized due to COVID-19 identified in the vaccine group and 16 in the control group ≥15 days after Dose 1, resulting in an estimate of vaccine efficacy of 87.6% (95% CI: 46.0 to 97.2%).

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The 2 hospitalizations in the vaccine group were 1 and 10 days post vaccination (median follow up: 115 days, range: 41–149).

Table 12. Estimates of vaccine efficacy against hospitalization, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]	0/6,307 (0.0)	9/6,297 (0.1)	100% (95% CI: 49.6 to NE)
≥15 days after Dose 2[c]	0/6,085 (0.0)	7/6,073 (0.1)	N/A

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

Deaths

As of the updated data cut-off date of December 7, 2020, there has been a single death due to COVID-19 identified in a study participant in the control group.

Asymptomatic infection and transmission

This was an exploratory analysis conducted only in clinical trial COV002 (UK). As part of the study protocol, beginning one week after receipt of Dose 1, study participants were asked to provide weekly self-administered nose or throat swabs for RT-PCR testing. Participants were asked to report symptoms when they appeared; however, the presence or absence of symptoms at the time of sample collection was not routinely collected. An asymptomatic infection was defined as a study participant with a swab virologically confirmed for SARS-CoV-2 and who reported no clinical trial–defined symptoms of confirmed COVID-19. Study participants with virologically confirmed SARS-CoV-2 infection, but who did not report whether or not they had symptoms were classified as "unknown symptoms".

Table 13. Estimates of vaccine efficacy against asymptomatic infection, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]			
	14/3,060 (0.5%)	15/3,064 (0.5%)	6.6% (-93.5 to 54.9%)
≥15 days after Dose 2[c]			
Any interval	8/2,377 (0.3%)	11/2,340 (0.5%)	26.9% (-81.5 to 70.6%)
4–12 weeks	N/A	N/A	37.7% (-90.1 to 79.6%)
>12 weeks	N/A	N/A	-4.3% (-416.5 to 79.0%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

An additional ad-hoc analysis combining study participants with SARS-CoV-2 asymptomatic infection or associated with unknown symptoms also failed to demonstrate the efficacy of the SD/SD regimen (3.9%, 95% CI: -72.1 to 46.4%), based on the identification of 22 cases in the vaccine group and 23 cases in the control group ≥15 days after Dose 2.

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Immunogenicity

Approximately 15% of the overall safety analysis set was targeted for inclusion in the immunogenicity analysis set. These analyses combined evidence from SD/SD and LD/SD dosing regimens, and may not completely align with the data from individual studies.

Humoral immune responses

Antibody responses, both binding and neutralizing, differed for seronegative and seropositive vaccine recipients. Vaccine recipients who were seropositive at baseline demonstrated high antibody titres 28 days after Dose 1 compared to seronegative recipients. Seronegative recipients demonstrated an increase in their immune responses 28 days after Dose 2. By contrast, seropositive recipients had decreased immune responses after Dose 2 compared to responses after Dose 1. However, immune responses for seropositive recipients at all time points were higher than those for seronegative recipients. The mechanism behind these differences, and their potential impact on vaccine efficacy and effectiveness remains unclear. A recently published article contains additional evidence on humoral responses [18].

Antibody responses, both binding and neutralizing, were lower in older adults (65+) than in younger adults after both the first and second dose of vaccine. Without a correlate of protection, the significance of these difference in antibody responses is unclear.

Cellular immune responses

Cellular immune responses were elicited by this vaccine. The first dose elicited Th-1 biased CD4+ T cells in both younger and older age groups. Younger vaccine recipients exhibited higher cellular immune responses than older age groups. Notably, the second vaccine dose did not augment cellular immune responses. The mechanism and the impact on vaccine efficacy and effectiveness remains unclear.

Anti-Vector immune responses

It is unclear to what extent pre-existing immunity to any adenovirus-based vaccine vector exists in the Canadian population and what impact that could have on adenovirus based vaccine safety and efficacy. It is also unclear as to what extent immunization with adenovirus-based vaccines elicits anti-vector immune responses and what impact that could have on homologous or heterologous booster doses with adenovirus-based vaccines. Evidence for a viral vector vaccine based on human adenovirus 5 (not authorized in Canada) indicated that vaccine recipients with high pre-existing immunity to the adenovirus vector had lower anti-SARS-CoV-2 immune responses [30]. The AstraZeneca COVID-19 vaccine uses a modified chimpanzee adenovirus vector (ChAd). AstraZeneca found no correlation between anti-ChAd neutralizing antibody responses and anti-SARS-CoV-2 immune responses. It also found that neutralizing antibody levels were not boosted after receiving the second dose. However, neutralization is not the only anti-vector immune response that could impact vaccine-induced immunity. It remains unclear if immune responses to the ChAd vector will impact the efficacy or effectiveness of this vaccine.

Unofficial

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Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 23,745 participants of which 12021 received at least one dose of the AZ COVID-19 vaccine and 11724 received a control. The safety analyses were conducted in different analysis sets. Solicited adverse events occurring within 7 days after any dose were assessed among 2648 vaccine recipients who received at least one dose (SD) and 2497 control recipients. Approximately one third of study participants received their second vaccine dose within 6 weeks of receiving Dose 1. The majority (~90%) of study participants in the safety cohort were less than 65 years of age. The median duration of follow-up was 105 days post-Dose 1 and 62 days post-Dose 2.

Solicited Local Reactions

Solicited local injection site AEs were reported by 74.7% of evaluated participants within the first 7 days following any vaccine dose. Pain and tenderness were most frequently reported (54.2% and 63.7%, respectively) followed by warmth (17.7%), bruising (17.3%), redness (14.0%), pruritus (12.7%), and swelling (10.0%). The majority of solicited local reactions among vaccine recipients were mild or moderate in severity, with any grade 3 or 4 reactions being reported by ≤9.5% of participants. No Grade 4 AEs were reported. Local reactions were generally milder and reported less frequently after the second dose of the vaccine. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose within 6 weeks following Dose 1 (38.0% versus 58.3% to 74.3% when Dose 2 was provided after ≥6 weeks).

Solicited Systemic Reactions

Solicited systemic AEs were reported by 73.0% of evaluated participants within the first 7 days following any vaccine dose. The most common systemic solicited systemic AEs were fatigue (53.1%) and headache (52.6%). Other frequently reported systemic solicited AEs were muscle pain (44.0%), malaise (44.2%), feverishness (33.6%), chills (31.9%), joint pain (26.4%), nausea (21.9%) and fever ≥38.0°C (7.9%). Overall, the frequency of any grade 3 or 4 reaction was ≤8.3%. The single reported Grade 4 event was fever > 40°C. Across study groups, AEs were milder and reported less frequently after the second vaccine dose. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose at <6 weeks following Dose 1 (37.6% versus. 49.2% to 67.1% when Dose 2 was provided after at ≥6 weeks).

Unsolicited Serious Adverse Events

SAE were reported by less than 1% of study participants and was similar between the vaccine and control groups (0.7% and 0.8%, respectively). There were no clear imbalances by System Organ Class (SOC). The most frequently reported SAEs by SOC were 'Infections and Infestations' (0.1% vs 0.2%) and 'Injury, poisoning and procedural complications' (<0.1% vs 0.1%).

Two SAEs (pyrexia, transverse myelitis) in the vaccine recipients were considered related to the vaccine by the study investigators. The case of pyrexia (40.5°) occurred 2 days after dose 1 and resolved the same day following the administration of acetaminophen. The event of transverse myelitis occurred in a 37-year-old female with a family history of Charcot-Marie-Tooth type 1a (mother and brother). The participant received two doses of study intervention 77 days apart. Two weeks after the second dose, the participant developed sensory changes and clumsiness. Magnetic resonance imaging showed a lesion consistent with transverse myelitis or anterior spinal infarction. A third SAE was originally identified (C-reactive protein increase); However,

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after the cut-off date, causality for the SAE of C-reactive protein increase was updated by the investigator to be not treatment related.

Other serious adverse events

Demyelinating events
An event of multiple sclerosis occurred in a 37-year-old female who developed sensory symptoms about 10 days after first (and only) vaccination. The clinical episode had a duration of 3 weeks. Further follow up with MRI of spine and brain showed an acute spinal lesion and older cerebral lesions, revealing pre-existing, but previously unrecognized, multiple sclerosis.

Death
A total of 6 deaths were reported among study participants (2 in the vaccine group and 4 in the control group). The cause of death among vaccine recipients included malignant neoplasm and fungal pneumonia, with neither considered to be related to the study intervention by the investigators.

Vaccine-Induced Immune Thrombotic Thrombocytopenia
Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported globally following post-licensure use of AstraZeneca COVID-19 vaccine. The majority of cases identified so far have been in women under the age of 55 years - although cases in men and individuals between 55 and 80 years of age have also been reported- and have mostly occurred between 4 and 14 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the AstraZeneca COVID-19 vaccine may trigger VITT is still under investigation. At this time, no other predisposing factors have consistently been identified in patients who develop VITT. The rate of this adverse event is still to be confirmed but is currently estimated to be between 1 in 26,000 and 1 in 500,000. Additional information is currently being gathered to characterize the rate of VITT more accurately. Based on available information, the case fatality of VITT is between 21 to 60%; Case fatality may vary with increased awareness of the adverse event and appropriate early treatment.

Effectiveness in individuals ≥65 years of age

In the absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on real-world vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized below.

All three observational studies assessed one dose of either the Pfizer-BioNTech or the AstraZeneca vaccines in the United Kingdom. The results below pertain only to the AstraZeneca portion of the studies. The studies were conducted during the period when SARS-CoV-2 B.1.1.7 variant was rapidly becoming the dominant circulating strain in their respective geographic regions. Approximately 50% of laboratory samples were found to have a profile consistent with the B.1.1.7 variant in early December, 2020 in England, and 43% in Scotland in early January, 2021. By mid to late February, the SARS-CoV-2 B.1.1.7 variant

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represented almost 100% of circulating strains in England, and was considered the dominant strain in Scotland.

Overall summary of evidence:

In adults 65 years of age and over, observational data available from pre-prints from the United Kingdom have shown a reduction in the risk of symptomatic disease and hospitalization starting from two weeks following one dose of AstraZeneca vaccine.

Detailed summary of each study:

1. Hyams et al., Assessing the Effectiveness of BNT162b2 and ChAdOx1nCoV-19 COVID-19 Vaccination in Prevention of Hospitalisations in Elderly and Frail Adults: A Single Centre Test Negative Case-Control Study. SSRN-Lancet **preprint.** March 3, 2021. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3796835

Description: Test-negative case control study of hospitalized people ≥80 years of age (many of whom were frail with comorbidities) in two hospitals in Bristol, United Kingdom. Vaccination was determined by record linkage and adjustment was conducted for a number of factors. Vaccine effectiveness against hospitalization was assessed in those who had been vaccinated ≥14 days before symptom onset.

Results: One-dose vaccine effectiveness of 80.4% (95% CI: 36.4 – 94.5) against hospitalization occurring within 14 or more days (maximum 53 days) after one dose of AstraZeneca COVID-19 vaccine among patients ≥80 years of age.

Review:

- Vaccination was determined by record linkage and clinical information was obtained from records by individuals who are blinded to the participants SARS-CoV-2 results. These are methodological strengths of this study.
- The authors performed a sensitivity analysis of those with symptom onset < 14 days after vaccination and did not find an effect, which is expected as this is too early for the vaccine to work, and adds strength to differences they note 14 days or more after vaccination.
- Eligible cases and controls were selected from the medical admission list, and it is unclear how this was done.
- Separate analyses seemed to have been conducted for AstraZeneca and Pfizer-BioNTech but it is unclear how the study subjects for each analysis were assigned.

2. Lopez Bernal et al., Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. medRxiv. **Preprint** March 2, 2021. https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

Description: Test negative-case control study using linked surveillance data in the United Kingdom among patients ≥70 years of age. PCR tests were within 10 days of onset of symptoms. For those who were vaccinated, cases and controls were assessed by time since

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vaccination to onset of symptoms, controlling for a number of factors. The impact of vaccination on hospitalization in individuals ≥80 years of age was also assessed in those who tested positive

Results: One-dose vaccine effectiveness against symptomatic PCR confirmed SARS-CoV-2 infection in the adjusted analysis was 22% (95% CI: 11 – 32) 14 to 20 days after vaccination and gradually rose up to 73% (95% CI: 27 – 90) 35 or more days (maximum 48 days) after vaccination. As well as the effect against symptomatic disease, in individuals who were ≥80 years of age there was an additional 37% protection against hospitalization within 14 days of a positive test in those 14 or more days from their first dose of vaccine compared to those who were unvaccinated.

Review:

- Record linkage using large data sets is a strength of this study.
- A relatively small number of subjects were included in the AstraZeneca COVID-19 vaccine analysis at later time periods, particularly in the time period of 35 or more days after vaccination when the vaccine effectiveness was the highest.
- The unadjusted and adjusted odds ratio are considerably different in the AstraZeneca COVID-19 analysis reflecting differences between study groups.
- Demographic and clinical information for cases and controls and vaccinated and unvaccinated individuals were not provided.

3. Vasileiou et al. Effectiveness of first dose COVID-19 vaccines against hospital admissions in Scotland effectiveness findings from Scotland: national prospective cohort study of 5.4 million people. SSRN-Lancet **preprint.** February 19, 2021. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789264

Description: A prospective observational cohort study using record linkage between databases, including vaccination, hospitalization and laboratory records for the population in Scotland, with adjustment for a number of factors. Although the study included those ≥18 years of age, the AstraZeneca vaccine was mostly administered to participants aged 65 years and older. Age-specific vaccine effectiveness is provided but did not distinguish between the Pfizer-BioNTech and AstraZeneca vaccines, which were both studied, although those ≥80 years of age mainly received the AstraZeneca vaccine.

Results: The effectiveness of one dose of the AstraZeneca vaccine against hospitalization was 74% (95% CI: 66 – 81) 14 to 20 days after vaccination and rose up to 94% (95% CI: 73 – 99) 28 to 34 days after vaccination. In patients ≥80 years of age, the authors found a peak vaccine effectiveness (VE) of 81% (95% CI: 65 – 90) against hospitalization within 28 to 34 days after one dose of vaccine that was mainly the AstraZeneca vaccine.

Review:

Due to concerns with methodological weaknesses in this study, NACI did not use these results to inform its recommendations. Methodological weaknesses include:

- AstraZeneca COVID-19 vaccine effectiveness against hospitalization was high (70%) 7 to 13 days after vaccination, which is biologically implausible, as 7 to 13 days would be too early to expect protection from infection or hospitalization as a result of vaccination, suggesting methodological concerns and making the high vaccine effectiveness results at later time periods (94% at 28 to 34 days) challenging to interpret.

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- The number of people vaccinated with the AstraZeneca COVID-19 vaccine is small in the period 28 days and more from vaccination.
- As vaccine roll out initially targeted priority groups at higher risk of severe disease or exposure, adjustments for potential confounding factors conducted during the statistical analyses might not have adequately controlled for all the differences between vaccinated and unvaccinated individuals. Demographic and risk factor comparisons between vaccinated and unvaccinated groups were not provided separately for each vaccine.
- Hospital admission was defined as: COVID-19 as the main cause of admission or hospitalization within 28 days of a positive PCR SARS-CoV-2 test. Hospital admission for COVID-19 is a less specific criteria for determining COVID-19 hospitalization and the proportion of cases defined using that criteria are not provided.
- Although product specific vaccine effectiveness and age specific vaccine effectiveness are both provided separately, product specific vaccine effectiveness by age was not provided.
- Record linkage using large data sets is a strength of this study.

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APPENDIX D: FREQUENCY OF SOLICITED ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 VACCINES IN CLINICAL TRIALS

Table 14. Frequency of solicited local adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine				Moderna COVID-19 Vaccine			
	Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	NS	NS	NS	NS	NS	NS	NS	NS
Redness/erythema	Common	Common	Common	Rare	Common	Common	Uncommon	Uncommon
Swelling	Common	Common	Rare	Rare	Common	Very Common	Uncommon	Uncommon
Lymphadenopathy[b]/ Axillary swelling and tenderness	NS	NS	NS	NS	Very Common	Very Common	Common	Common
Warmth	NS	NS	NS	NS	NS	NS	NS	NS
Pruritis	NS	NS	NS	NS	NS	NS	NS	NS
Induration	NS	NS	NS	NS	NS	NS	NS	NS

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Lymphadenopathy was not a solicited adverse event for the Pfizer BioNTech COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix A for more details.

Table 15. Frequency of solicited local adverse events in authorized populations for AstraZeneca COVID-19 vaccine[a]

AEFI	AstraZeneca COVID-19 Vaccine			
	Vaccine		MenACWY control	
	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common
Tenderness	Very Common	Very Common	Very Common	Very Common

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Redness/erythema	Very Common	Common	Common	Uncommon
Swelling	Common	Common	Common	Common
Lymphadenopathy[b]/ Axillary swelling and tenderness	NS	NS	NS	NS
Warmth	Very Common	Common	Very Common	Common
Pruritis	Very Common	Common	Common	Common
Induration	Common	Common	Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Lymphadenopathy was not a solicited adverse event for the AstraZeneca COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix C for more details.

Table 16. Frequency of solicited systemic adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine				Moderna COVID-19 Vaccine			
	Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Very Common	Common	Common	Common	Very Common	Common	Common
Joint Pain	Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Very Common
Fever[b]	Common	Very Common	Uncommon	Uncommon	Uncommon	Very Common	Uncommon	Uncommon
Feverishness[b]	NS	NS	NS	NS	NS	NS	NS	NS
Diarrhea	Common	Common	Common	Common	NS	NS	NS	NS
Nausea and/or Vomiting[c]	Uncommon	Common	Uncommon	Uncommon	Common	Very Common	Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

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[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

Table 17. Frequency of solicited systemic adverse events in authorized populations for AstraZeneca COVID-19 vaccine[a]

AEFI	AstraZeneca COVID-19 Vaccine			
	Vaccine		MenACWY control	
	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Common	Common	Common
Joint Pain	Very Common	Very Common	Common	Common
Fever[b]	Common	Common	Uncommon	Uncommon
Feverishness[b]	Very Common	Common	Common	Common
Diarrhea	NS	NS	NS	NS
Nausea and/or Vomiting[c]	Very Common/ Common	Common/ Uncommon	Very Common/ Uncommon	Common/ Uncommon

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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APPENDIX E: BENEFIT-RISK ASSESSMENT FOR THE USE OF ASTRAZENECA COVID-19 VACCINE IN A PUBLIC HEALTH CONTEXT

A benefit-risk analysis was conducted to determine if the benefit of earlier vaccination with the AstraZeneca COVID-19 vaccine (instead of waiting for a later age-based mRNA vaccine) outweighs the risk of harms from Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). In this analysis, the possible benefits were defined as the potential ICU admissions and deaths due to COVID-19 that could be prevented with the use of AstraZeneca COVID-19 vaccine, instead of waiting for a later mRNA vaccine. The potential harm was the development of VITT events requiring ICU admission and resulting in death. An age-based analysis was conducted to account for differences in risk for COVID-19 disease and development of severe outcomes by age.

Methodology

The approach to the benefit-risk analysis was based on a similar analysis conducted by the Winton Centre for Risk and Evidence Communication, using Canadian-based data where available.

Calculation of potentially prevented COVID-19 ICU admissions and death

Four scenarios were considered, with daily incidence rates per 10,000 corresponding to very low to high activity levels in the national COVID-19 Activity Levels Framework. These daily rates were then converted to weekly incidence rates (see Table 1). A very high activity level was assessed doubling the high activity level. Analysis was completed April 16, 2021.

The weekly number of expected cases (per 100,000) of ICU admission and deaths due to COVID-19 were calculated by applying the age-based proportions of cases that have been observed in Canadian surveillance data (cumulative to April 9, 2021) in 10-year age bands from 20 to 69 years of age against the weekly COVID-19 incidence defined by the four scenarios in Table 1. From the surveillance data, we obtained the observed age-based proportion of cases that became hospitalized and hospitalized cases that were admitted into ICU, as well as the case fatality estimate (see Table 2) and applied these to the weekly incidence rates. We assumed a vaccine efficacy of 80% against severe outcomes for the AstraZeneca vaccine.

In the context of vaccine supply in Canada, the total number of events potentially prevented were calculated by multiplying the number of weekly events by the number of weeks each age band was estimated to have to wait before being able to receive an mRNA vaccine (see Table 3).

Calculation of potential VITT cases

To assess the potential harm of receiving the AstraZeneca COVID-19 vaccine, we assumed a fixed rate of VITT events across the age groups due to limited available information on age-based risk. With the uncertainty around the incidence of VITT events, we assessed scenarios with a rate of 1 case per 250,000 AstraZeneca doses administered and 1 case per 100,000 doses administered, where 100%

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of cases would require ICU admission. When comparing mortality due to COVID-19 and mortality due to VITT, we assumed that 25% and 40% of VITT cases died to account for the current uncertainty.

Table 18. Daily and weekly incidence rates of infection under four different scenarios used for benefit-risk analysis

Scenario	Daily incidence per 10,000	Weekly incidence per 100,000
Very low	0.06	4.20
Low	0.30	21.00
Moderate	0.75	52.50
High	3.00	210.00
Very high[a]	6.00	420.00

[a] The very high scenario was created for the purposes of this benefit-risk analysis only, and is not based on a category of activity within the COVID-19 Activity Levels Framework

Table 19. Proportion of COVID-19 events of interest by age group based on Canadian surveillance data

Age Group	Cases	Proportion of cases who are hospitalized	Proportion of hospitalized who require ICU	Proportion of cases who die
20 to 29	18.80%	0.94%	13.83%	0.02%
30 to 39	16.10%	1.79%	15.61%	0.05%
40 to 49	14.65%	2.69%	20.91%	0.13%
50 to 59	13.33%	4.99%	25.06%	0.47%
60 to 69	8.40%	10.62%	27.17%	2.15%

Table 20: Projected wait time to mRNA vaccines from mid-April 2021 based on anticipated supply of mRNA vaccines

Age Group	Projected wait time (weeks)
20 to 29	7
30 to 39	6
40 to 49	4
50 to 59	3
60 to 69	1

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Results

Table 21. VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to COVID-19 ICU admissions prevented by early AstraZeneca vaccination under four different scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of COVID-19 infection)				
		Very low (0.06 per 10,000)	Low (0.30 per 10,000)	Moderate (0.75 per 10,000)	High (3 per 10,000)	Very high (6 per 10,000)
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.01	0.03	0.07	0.29	0.57[a]
30 to 39	0.40	0.01	0.05	0.11	0.45[a]	0.91[a]
40 to 49	0.40	0.01	0.06	0.14	0.55[a]	1.11[a]
50 to 59	0.40	0.02	0.08	0.21	0.84[a]	1.68[a]
60 to 69	0.40	0.01	0.04	0.10	0.41[a]	0.81[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 22. VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to COVID-19 ICU admissions prevented by early AstraZeneca vaccination under four different scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of COVID-19 infection)				
		Very low (0.06 per 10,000)	Low (0.30 per 10,000)	Moderate (0.75 per 10,000)	High (3 per 10,000)	Very high (6 per 10,000)
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.01	0.03	0.07	0.29	0.57
30 to 39	1.00	0.01	0.05	0.11	0.45	0.91
40 to 49	1.00	0.01	0.06	0.14	0.55	1.11
50 to 59	1.00	0.02	0.08	0.21	0.84	1.68
60 to 69	1.00	0.01	0.04	0.10	0.41	0.81

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

Table 23. VITT deaths by age group (based on VITT rate of 1 per 250,000) compared to deaths due to COVID-19 prevented by early AstraZeneca vaccination under four different scenarios

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Age Group	Expected deaths due to VITT per 100,000		Scenario activity level (daily incidence of COVID-19 infection)				
	25% case fatality	40% case fatality	Very low (0.06 per 10,000)	Low (0.30 per 10,000)	Moderate (0.75 per 10,000)	High (3 per 10,000)	Very high (6 per 10,000)
			Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.10	0.16	0.00	0.00	0.01	0.04	0.09
30 to 39	0.10	0.16	0.00	0.01	0.02	0.08	0.17[a]
40 to 49	0.10	0.16	0.00	0.01	0.03	0.13[a]	0.26[b]
50 to 59	0.10	0.16	0.01	0.03	0.08	0.32[b]	0.63[b]
60 to 69	0.10	0.16	0.01	0.03	0.08	0.30[b]	0.61[b]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT only for the lower case fatality estimate

[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT for both case fatality estimates

Table 24. VITT deaths by age group (based on VITT rate of 1 per 100,000) compared to deaths due to COVID-19 prevented by early AstraZeneca vaccination under four different scenarios

Age Group	Expected deaths due to VITT per 100,000		Scenario activity level (daily incidence of COVID-19 infection)				
	25% case fatality	40% case fatality	Very low (0.06 per 10,000)	Low (0.30 per 10,000)	Moderate (0.75 per 10,000)	High (3 per 10,000)	Very high (6 per 10,000)
			Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.25	0.40	0.00	0.00	0.01	0.04	0.09
30 to 39	0.25	0.40	0.00	0.01	0.02	0.08	0.17
40 to 49	0.25	0.40	0.00	0.01	0.03	0.13	0.26[a]
50 to 59	0.25	0.40	0.01	0.03	0.08	0.32[b]	0.63[b]
60 to 69	0.25	0.40	0.01	0.03	0.08	0.30[b]	0.61[b]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT only for the lower case fatality estimate

[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT for both case fatality estimates

Limitations of analysis

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There are some limitations to this analysis to consider when interpreting the benefit-risk estimates.

1) Each scenario is based on a constant incidence rate. However, the risk of COVID-19 is dynamic and difficult to predict. As a result, the estimated benefits of preventing COVID-19 outcomes with AstraZeneca COVID-19 vaccination compared to waiting for an mRNA vaccine will be more uncertain for age groups with the longer wait times for mRNA vaccines.
2) The risks of ICU admission and deaths were based on the age distribution of cases in surveillance data and unreported cases are not uniformly distributed across age groups. Moreover, ICU admission status was only known for approximately 33% of submitted cases as of April 14, 2021. Thus, there is uncertainty in the relative benefits between age groups in preventing ICU admissions with AstraZeneca vaccination compared to waiting for an mRNA vaccine.
3) This analysis did not account for ICU capacity limits. In scenarios where incidence rates result in overflow of ICU capacity this analysis will underestimate the benefits of preventing deaths with AstraZeneca COVID-19 vaccination. However, if such a scenario is considered likely, then the benefit-risk estimates from the high scenario may be most applicable.
4) Estimates of VITT incidence and mortality are still highly uncertain and may change as evidence continues to emerge.
5) Time to wait to receive an mRNA vaccine assumes vaccine administration to be 100% efficient (i.e., weekly supply is consumed by the end of the week). If vaccine uptake is delayed or slower than anticipated, the cumulative risks of COVID-19 outcomes will increase, particularly in age groups facing longer wait times for mRNA vaccines.
6) Administration of AstraZeneca COVID-19 vaccine to each age group is assumed to take place in mid-April 2021. Any delay in administering the vaccine to a particular age group shortens the time period to wait for mRNA and therefore reduces the benefit of AstraZeneca COVID-19 vaccine.

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An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Recommendations on the use of COVID-19 Vaccines

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PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence-based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include: economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

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TABLE OF UPDATES

This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, as evidence on these vaccines and COVID-19 evolves, and as recommendations from NACI evolve based on this evidence. This table summarizes the updated information provided in the current version of this document since the publication of the last version of the document on April 23, 2021.

A complete list of changes to this document can be found in the Table of updates: Recommendations on the use of COVID-19 vaccines web page. Complete previous versions of this document are archived and are available through the National Advisory Committee on Immunization (NACI): Statements and publications web page under COVID-19.

Section	Update	Date
Vaccines	All sub-sections under the section "Vaccines" have been updated to include evidence or information from the product monograph related to the Janssen COVID-19 vaccine. This includes: • Table 1. COVID-19 vaccines authorized for use in Canada • Efficacy and Effectiveness • Immunogenicity • Vaccine administration • Storage requirements • Vaccine safety and adverse events following immunization	2021-05-03
Vaccines	A section on immunogenicity in individuals previously infected with SARS-CoV-2 has been included.	2021-05-03
Vaccines	A section on adverse events following the second dose of COVID-19 vaccine in individuals previously infected with SARS-CoV-2 has been included.	2021-05-03
Recommendations	NACI's overarching recommendation on the use of COVID-19 vaccines has been updated to include guidance on the use of the Janssen COVID-19 vaccine. The summary of evidence and rationale for this recommendation has been updated.	2021-05-03
Recommendations	NACI's preferential recommendation for the use of mRNA vaccines in pregnancy has been highlighted given the complexities of the clinical management of Vaccine Induced Immune Thrombotic Thrombocytopenia (VITT) in pregnancy should it occur after vaccination with a viral vector vaccine. In addition, preliminary data on mRNA vaccines administered in pregnancy is now available with no safety signals detected. The summary of evidence and rationale for the pregnancy and breastfeeding	2021-05-03

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Section	Update	Date
	recommendations have been updated with additional information from Developmental and Reproductive Toxicity (DART) animal studies for Janssen COVID-19 vaccine. The evidence summary has also been updated to reflect current research on COVID-19 vaccination during pregnancy and breastfeeding.	
Management options for COVID-19 vaccines authorized and available for use in Canada	Table 5 has been updated with data for Janssen COVID-19 vaccine.	2021-05-03
Appendix D	Evidence on the efficacy, immunogenicity and safety of the Janssen COVID-19 vaccine has been added in a new appendix.	2021-05-03
Appendix E	Tables capturing the frequency of solicited adverse events following immunization in clinical trials with mRNA and viral vector COVID-19 vaccines have been updated.	2021-05-03
Appendix F	The benefit risk assessment for the use of Janssen COVID-19 vaccine in a public health context has been added.	2021-05-03
Appendix G	Information on pregnancy and COVID-19 vaccine registries has been added in a new appendix.	2021-05-03

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SUMMARY OF INFORMATION CONTAINED IN THIS NACI STATEMENT

The following highlights key, current information for immunization providers on COVID-19 vaccines. The evidence on COVID-19 disease and vaccines is evolving. Evidence from clinical trial data is limited due to limitations in the size and duration of follow-up of trial populations. However, clinical trials and studies in the real-world setting are ongoing. NACI will continue to monitor the evidence and update its recommendations as needed. Please refer to the remainder of the Statement for details.

What

Disease

- Novel coronavirus disease 2019 (COVID-19) is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.
- Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors that may intersect. Risk factors for exposure and severe disease may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations.

Currently authorized and available vaccines
(Pfizer BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine)

- mRNA vaccines are authorized for use in Canada for individuals 16 years of age and older (Pfizer-BioNTech COVID-19 vaccine) or 18 years of age and older (Moderna COVID-19 vaccine).
- Non-replicating viral vector vaccines are authorized for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine and Janssen COVID-19 vaccine).
- In clinical trials, all COVID-19 vaccines are efficacious in the short-term against symptomatic, confirmed COVID-19 disease; trials are ongoing. mRNA COVID-19 vaccines have demonstrated high efficacy (approximately 94-95%). The AstraZeneca COVID-19 vaccine has demonstrated an average efficacy of approximately 62% in those 18-64 years of age. In adults 65 years of age and older who received one dose of AstraZeneca, real-world observational data of vaccine effectiveness have shown a reduction in the risk of symptomatic disease and hospitalization. The Janssen COVID-19 vaccine has demonstrated efficacy of 67% against confirmed symptomatic moderate to severe/critical COVID-19 infection based on trials conducted in South Africa and Brazil while B.1.335 and P.2 were circulating, respectively. There is currently limited evidence on the duration of protection and on the efficacy of these vaccines in reducing transmission of SARS-CoV-2, although studies are ongoing. Evidence of protection against asymptomatic SARS-CoV-2 infection is emerging for the mRNA and Janssen vaccines.
- Evidence of varying protection offered by COVID-19 vaccines against SARS-CoV-2 variants is evolving. To date, evidence has emerged that the Pfizer-BioNTech and AstraZeneca vaccines offer protection against the B.1.1.7 variant of concern first identified

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in the UK. There is evidence that the Janssen vaccine offers some protection against the B.1.351 variant of concern first identified in South Africa as well as the P.2 variant of interest first identified in Brazil. There is evidence that the AstraZeneca vaccine does not offer protection against the B.1.351 variant.

- For all vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. In clinical trials of mRNA vaccines, some adverse events, including fever, are more frequent after the second dose; this was not the case with the AstraZeneca COVID-19 vaccine.
- Rare cases of a specific syndrome that involves serious blood clots (at unusual sites such as cerebral venous sinus thrombosis) associated with thrombocytopenia have recently been reported after vaccination with viral vector vaccines. These cases often occur between 4 and 28 days after receipt of the vaccine. Early identification and appropriate treatment are critical. Investigations to better understand this syndrome, often referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), are ongoing.
- There is currently minimal evidence to inform on differences in vaccine efficacy, effectiveness, or safety between individuals with and those without prior evidence of SARS-CoV-2 infection at the time of vaccination.

Who

NACI makes the following recommendations:

A complete series with an mRNA COVID-19 vaccine *should be* preferentially offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered.

A complete series with a viral vector COVID-19 vaccine *may be* offered to individuals 30 years of age and older without contraindications only if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine AND all the following conditions apply:

a) The benefit-risk analysis* determines that the benefit of earlier vaccination with a viral vector COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
b) The benefits and relative risk* and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as the availability of other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND
c) There will be substantial delay to receive an mRNA vaccine.

Note: Provinces and territories should adapt the age limit based on their local epidemiology.

*See Risk Assessment Tool and Management Options Table to assist with this determination

A complete vaccine series with a currently authorized COVID-19 vaccine *may be* offered to:

- Individuals in the authorized age group without contraindications to the vaccine who have had previously polymerase chain reaction (PCR)-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had previously PCR-confirmed SARS-CoV-2 infection. Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.

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For some specific populations who were either excluded from, or were represented by small numbers of participants in clinical trials, NACI recommends that a complete vaccine series with a currently authorized COVID-19 vaccine may be offered, if a risk assessment deems that the benefits of vaccination outweigh the potential risks for the individual (e.g., where the risk of severe outcomes of COVID-19 and/or risk of exposure to SARS-CoV-2 is high) or for the fetus/infant (in the case of pregnancy/breastfeeding) and if informed consent includes discussion about the insufficient evidence in these populations:

- Immunosuppressed due to disease or treatment
- Individuals with an autoimmune condition
- Pregnant or breastfeeding
- Adolescents 12 to 15 years of age (Only Pfizer-BioNTech COVID-19 vaccine may be offered)

These recommendations may change as more evidence on safety and/or efficacy/effectiveness in these populations becomes available.

NACI also recommends that:

- All individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time, due to insufficient evidence on the duration of protection and effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.
- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.
- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded or remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.
- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, seniors living in congregate care settings, children and adolescents) is recommended.

NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization:

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- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.
- Jurisdictions should ensure close and rapid monitoring of safety, coverage and effectiveness of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.
- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

How

- Currently authorized and available COVID-19 vaccines are administered intramuscularly in a two-dose schedule (Pfizer-BioNTech, Moderna, AstraZeneca) or in a one-dose schedule (Janssen).
- Attempts should be made to complete the vaccine series with the same vaccine product.
- Serologic testing is not needed before or after receipt of a COVID-19 vaccine to assess susceptibility to SARS-CoV-2 or immune response to the vaccine.
- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines at this time, unless other vaccines are required for post-exposure prophylaxis.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

Why

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption in Canada and worldwide.
- The authorized COVID-19 vaccines that are recommended for use by NACI in this Statement have been shown to be safe (although very rare cases of VITT reported following vaccination with the viral vector COVID-19 vaccines), efficacious against symptomatic laboratory confirmed COVID-19, and appear to protect against severe disease, hospitalization and death due to COVID-19.

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I. INTRODUCTION

The overall goal of Canada's pandemic response is to minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic. The goal of Canada's COVID-19 immunization response is: To enable as many Canadians as possible to be immunized against COVID-19 as quickly as possible, while ensuring that high risk populations are prioritized.

This guidance document will provide recommendations on the use of authorized COVID-19 vaccines as they are approved and available for use in Canada, and as evidence on these vaccines evolves.

There are four COVID-19 vaccines currently authorized for use in Canada:

1. The Pfizer-BioNTech COVID-19 vaccine was authorized for use in Canada on December 9, 2020.
2. The Moderna COVID-19 vaccine was authorized for use in Canada on December 23, 2020.
3. The AstraZeneca COVID-19 vaccine was authorized for use in Canada on February 26, 2021.
    - Health Canada authorized two manufacturers to produce this vaccine developed by AstraZeneca and Oxford University: AstraZeneca and Serum Institute of India (SII). NACI has not specifically reviewed evidence for the SII vaccine, but Health Canada has deemed SII and AstraZeneca vaccines to be comparable. Authorization of the SII COVID-19 vaccine (COVISHIELD) was based on its comparability to the AstraZeneca COVID-19 vaccine as determined by evaluation and direct comparison of manufacturing processes and controls and the quality characteristics of the two products. The results of this comparison by Health Canada determined that the two products were sufficiently similar and that the efficacy, immunogenicity and safety of COVISHIELD could be inferred from the non-clinical and clinical studies from the AstraZeneca COVID-19 vaccine.
4. The Janssen COVID-19 vaccine was authorized for use in Canada on March 5, 2021.

The evidence on COVID-19 and COVID-19 vaccines has been rapidly evolving. To date, NACI has published the following evidence-informed guidance:

1. Research priorities for COVID-19 vaccines to support public health decisions to inform clinical trials of candidate COVID-19 vaccines to protect against infection, serious illness, and deaths caused by SARS-CoV-2.
2. Preliminary guidance on key populations for early COVID-19 immunization to plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.
3. Guidance on the prioritization of initial doses of COVID-19 vaccine(s) for the efficient and equitable prioritization of initial doses of COVID-19 vaccines to assist with the planning for allocation of the first COVID-19 immunization programs.
4. Guidance on the prioritization of key populations for COVID-19 immunization to provide guidance for the equitable, ethical, and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others.
5. Rapid response: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada to maximize the number of individuals

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benefiting from the first dose of vaccine by extending the interval for the second dose up to four months after the first. This was followed by a more comprehensive NACI statement providing a detailed overview of the evidence and considerations leading to NACI's recommendation.

6. Rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults (AstraZeneca vaccine should not be used in adults under 55 years of age at this time) while the safety signal of Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) [now and hereafter referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)] following vaccination with AstraZeneca COVID-19 vaccine is investigated further.
7. Recommendations on the use of COVID-19 vaccine initially published on December 12, 2020 and updated iteratively as new evidence becomes available and with the authorization of additional COVID-19 vaccines. This statement reflects the most up to date guidance.

Guidance Objective

The objective of this advisory committee statement is to provide evidence-informed guidance on the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada. This evergreen document will be updated as COVID-19 vaccines are authorized and become available for use in Canada, and as the evolution of evidence on these vaccines or the pandemic situation warrants changes in guidance. In this guidance document, the evidence and rationale for recommendations as well as current knowledge gaps will be summarized. Evidence summaries on vaccine characteristics for specific COVID-19 vaccines will be included in appendices.

II. METHODS

Details of NACI's recommendation development process can be found elsewhere [1, 2].

In brief, the broad stages in the preparation of this NACI advisory committee statement included:

1. Knowledge synthesis
2. Synthesis of the body of evidence of benefits and harms, considering the quality of the synthesized evidence and magnitude and certainty of effects observed across the studies
3. Translation of evidence into recommendations.

In order to develop comprehensive, appropriate immunization program recommendations, NACI considers a number of factors. In addition to critically appraising evidence on burden of disease and vaccine characteristics such as safety, efficacy, immunogenicity and effectiveness, NACI uses a published, peer-reviewed framework and evidence-informed tools to ensure that issues related to ethics, equity, feasibility, and acceptability (EEFA) are systematically assessed and integrated into its guidance [2]. The NACI Secretariat applied this framework with accompanying evidence-informed tools (Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, Acceptability Matrix) to systematically consider these programmatic factors for the development of clear, comprehensive, appropriate recommendations for timely, transparent decision-making. For details on the development and application of NACI's EEFA Framework and evidence-informed tools (including the Ethics Integrated Filters, Equity Matrix, Feasibility Matrix, and Acceptability Matrix), please see https://doi.org/10.1016/j.vaccine.2020.05.051.

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For this advisory committee statement, NACI used the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) framework to develop population-focused recommendations. Further information on this framework can be found in the GRADE handbook, available at: https://training.cochrane.org/resource/grade-handbook

NACI reviewed and approved the key policy questions used to guide recommendation development on November 25, 2020 and rated the outcomes for their importance for decision-making. With evolving evidence, NACI rated outcomes again on March 21, 2021. The Canadian Immunization Committee (CIC) provided feedback on the key policy questions to ensure alignment with program needs. Important ethical considerations relating to the key policy questions were presented on November 26, 2020, December 15, 2020, January 26, 2021 and April 6, 2021 to the PHAC Public Health Ethics Consultative Group, who provided an assessment of ethical considerations that are relevant to the development of recommendations. Knowledge synthesis and quality appraisal were performed by the NACI Secretariat for unpublished clinical trial evidence and were informed by NACI's rating of the outcomes. Unpublished data from Phase 1, 2, and 3 clinical trials were presented to the High Consequence Infectious Disease Working Group and NACI for discussion. Proposed recommendations were then presented and approved at emergency NACI meetings. The description of relevant considerations, rationale for specific decisions, and knowledge gaps are described in the text.

Key Dates

- Pfizer-BioNTech COVID-19 vaccine was discussed on December 4, 2020 and related recommendations were approved on December 7, 2020.
- The Moderna COVID-19 vaccine was discussed on December 14, 2020 and related recommendations were approved on December 17, 2020.
- The AstraZeneca COVID-19 vaccine was discussed on January 19, 28, February 5, and February 24, 2021 and related recommendations were approved on February 24, 2021.
- Considerations regarding an extended interval between authorized vaccine doses in the context of limited vaccine supplies, and clarifications to recommendations for populations who were either excluded from or were represented by small numbers of participants in clinical trials were discussed on January 7, 2021 and were approved on January 8, 2021.
- Additional evidence on an extended interval of 4 months between authorized vaccine doses in the context of limited vaccine supplies was reviewed on February 8, 19, and 24-25, 2021. Related recommendations were approved on March 1, 2021. Between March 25 and March 28, 2021, NACI members revisited these recommendations as they relate to specific population groups.
- Additional evidence from observational studies of effectiveness of the AstraZeneca vaccine in those 65 years of age and over was reviewed on March 10, 2021. Related recommendations were approved on March 13, 2021.
- Evolving evidence of VITT following the use of AstraZeneca COVID-19 vaccine, including the Health Canada's safety assessment report issued on April 14, 2021, was formally reviewed on April 13,15, 17 and 20, 2021. Related recommendations were approved on April 20, 2021.
- The Janssen COVID-19 vaccine was discussed on March 16, 25 and April 13, 26, 2021, and recommendations were approved on April 30, 2021.

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III. EPIDEMIOLOGY

Information on COVID-19 is continually evolving. The following section will describe the current basis of knowledge, with an emphasis on the best available Canadian data where possible. To access the most recent updates to specific elements, please refer to the links below.

Disease description

Infectious agent

COVID-19 is caused by the SARS-CoV-2, which was first recognized in Wuhan, China in December 2019.

Transmission

Current evidence suggests that SARS-CoV-2 is spread through respiratory droplets and aerosols created when an infected person coughs, sneezes, sings, shouts, or talks. A person may be infectious for up to three days before showing symptoms.

More information on the transmission of SARS-CoV-2 can be found on the PHAC webpages for COVID-19: Main modes of transmission and COVID-19 signs, symptoms and severity of disease: A clinician guide

Variants of concern

Genetic mutations in the SARS-CoV-2 virus have been identified, some of which make the virus more infectious and transmissible. They may also affect the severity of disease and the level of protection offered by vaccines against them.

More information on the variants of concern (VOC) reported in Canada is available in the COVID-19 epidemiology update. The COVID-19 Weekly Epidemiological Update by the World Health Organization provides a summary on the global distribution and emerging evidence on VOC and variants of interest.

NACI will continue to monitor the epidemiology and evidence pertaining to VOC and COVID-19 vaccines.

Risk factors

Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or occupational settings), and some populations are at increased risk of severe disease and outcomes (e.g., hospitalization and death) due to various biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., socioeconomic status, belonging to a racialized population) factors that may intersect. Exposure and risk of severe disease factors may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate

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consequences for specific populations characterized by increased rates of infection and disease, severe illness, hospitalizations, and/or deaths.

Please see NACI's Advisory Committee Statement on Key Populations for Early COVID-19 Immunization and the Equity Matrix [3] for a summary of inequities associated with COVID-19, potential reasons for and intersections between these inequities, and suggested interventions to reduce inequities and improve access to vaccines. NACI's Guidance on the prioritization of key populations for COVID-19 immunization builds on the foundational framework for the equitable, ethical and efficient allocation of authorized COVID-19 vaccines in the context of staggered arrival of vaccine supply that will necessitate offering vaccines to some populations earlier than others. This guidance was informed by evolving evidence on risk factors for COVID-19.

Table 1 summarizes populations at risk of severe outcomes from COVID-19 (hospitalization and/or mortality) based on the results of an updated rapid review of evidence[4] from studies in Organisation for Economic Co-operation and Development (OECD) countries, as well as populations at increased risk of exposure to COVID-19 (due to inability to physically distance and/or reduced access to infection prevention and control measures) identified, in part, through Canadian reports (epidemiological or analytic).

The review by the Alberta Research Centre for Health Evidence (ARCHE) found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with age 60-69 years versus <60 years. A previous review by ARCHE found a moderate certainty of evidence for at least a 5-fold increase in mortality and hospitalization with age over 70 years (versus 45 years and younger). Studies treating age on a continuum or across small increments consistently found that risks for hospitalization and mortality increased with increasing age (e.g., approximately 2-6% and 5-10% relative increase in risk per year) [5].

The ARCHE review found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with a small number of medical conditions (classified as Level 1 in Table 1). The review found a low certainty of evidence for at least a 2-fold increase in mortality from COVID-19, and/or a low or moderate certainty of evidence for at least a 2-fold increase in hospitalization for a longer list of medical conditions (classified as Level 2 in Table 1). A moderate certainty of evidence of at least a 2-fold increase in hospitalization and mortality from COVID-19 in people living with two or more medical conditions was found. However, there is no direct evidence on the combination of medical conditions that increase this risk [5].

Caution should be taken when interpreting evidence of low certainty (e.g., for medical conditions listed as Level 2 in Table 1). As evidence accumulates, observed associations may change. For example, a previous rapid review by ARCHE [5] found low certainty evidence for at least a 2-fold increase in hospitalization or mortality for males, people with liver disease, and people with heart failure. As evidence has accumulated, there is now stronger evidence for little-to-no increased association of severe outcomes in these populations. The list of medical conditions included in Table 1 may not be comprehensive as it is based only on evidence from published studies included in the ARCHE review.

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Table 1. Summary of risk factors for severe outcomes from COVID-19 and increased risk of exposure to COVID-19

Increased risk of severe outcomes from COVID-19 (hospitalization/mortality) [a]	Increased risk of exposure to COVID-19 [4] (e.g., due to inability to physically distance/reduced access to IPC) [b]
Increasing age (strong evidence) (based on moderate certainty of evidence of ≥2-fold increase in mortality) • ≥60 years (particularly ≥ 70 years) [4]	• Residents and staff of congregate living settings that provide care for seniors • Frontline healthcare workers • Adults in Indigenous communities • Residents and staff of other congregate living settings (e.g., quarters for migrant workers, shelters, correctional facilities, group homes) • Adults in racialized and marginalized communities • First responders (e.g., police, firefighters) • Frontline essential workers who cannot work virtually
Medical conditions – Level 1 (strong evidence) [4] (based on moderate or high certainty evidence of ≥2-fold increase in mortality) • Down syndrome • End-stage kidney disease • Epilepsy • Motor neuron disease, multiple sclerosis, myasthenia gravis, Huntington's disease [d] • Type 1 and 2 diabetes	
Medical conditions – Level 2 (limited evidence) [4] **Level 2a** (based on low certainty of evidence of ≥2-fold increase in mortality • Cerebral palsy • Major psychiatric disorder (schizophrenia, schizoaffective disorder, or bipolar disorder); in combination with drug use for the condition in the past 6 months • Obesity class III (BMI 40 kg/m^2 or more) • Parkinson's disease • Sickle cell disease or severe immunodeficiency, transplant (any type) • Kidney transplant, • Recent bone marrow or stem cell transplant • Metastatic cancer • Recent/current chemotherapy or radiotherapy **Level 2b** (based on low or moderate certainty of evidence of ≥2-fold increase in hospitalization) • Previous cerebrovascular accident • Pregnancy (any stage) • Frailty (among community and non-community dwelling people; measured on scales that include items such as weight loss, exhaustion, physical activity, walking speed, grip strength, overall health, disability, presence of disease, dementia, falls, mental wellbeing)	

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Increased risk of severe outcomes (hospitalization/mortality)[c] and Increased risk of exposure [4]
• Long-term care residents • Visible minority groups (includes mainly South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean, Japanese)

[a] Identified through rapid review of evidence from OECD countries for an independent association with severe outcomes from COVID

[b] Identified, in part, through Canadian epidemiological reports

[c] Identified through rapid review of Canadian studies that may have an association with hospitalization and mortality from COVID-19. These studies may not have accounted for other covariates.

[d] These conditions were grouped within a single study; evidence for the individual conditions is either unavailable or of lower certainty.

The list of medical conditions in Table 1 may differ from those in other jurisdictions due to differences in local epidemiology and differing levels of evidence considered.

The evidence on risk factors for COVID-19 continues to evolve.

Spectrum of clinical illness

The median incubation period for non-variant SARS-CoV-2 has been estimated to be 5 to 6 days from exposure to symptom onset, with most individuals (97.5%) developing symptoms within 11.5 days of exposure. The incubation period ranges from 1 to 14 days.

Clinical presentation and symptoms of COVID-19 vary in frequency and severity. To date, there is no list of symptoms that has been validated to have high specificity or sensitivity for COVID-19.

More information on the spectrum of clinical illness is available on the PHAC webpage for COVID-19 signs, symptoms and severity of disease: A clinician guide.

Disease incidence

Global

Updated international data on COVID-19 cases and deaths is available at:
https://health-infobase.canada.ca/covid-19/international/

Weekly epidemiological updates highlighting key global, regional and country-level data on COVID-19 cases and deaths are available from the World Health Organization (WHO) at:
https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

National

Updated national, provincial and territorial-level data on COVID-19 cases and deaths in Canada over time is available from the PHAC webpage on Coronavirus disease (COVID-19): Outbreak update.

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IV. VACCINES

The following section summarizes information about COVID-19 vaccines authorized for use in Canada. More detailed vaccine-specific information is included in Appendices A through D. The current landscape of all candidate COVID-19 vaccines in clinical evaluation can be found on the WHO webpage Draft landscape of COVID-19 candidate vaccines. Under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, Health Canada can make regulatory decisions for COVID-19 vaccines that have completed Phase 3 clinical trials for authorized use in Canada.

Most vaccine candidates in development that may become authorized for use in Canada use various technologies to deliver SARS-CoV-2 spike protein to vaccine recipients. This protein is expressed on the surface of the SARS-CoV-2 virus and is a major target for binding and neutralizing antibodies as well as cell-mediated immune responses.

mRNA vaccines

COVID-19 vaccines that use messenger RNA (mRNA) platforms contain modified nucleotides that code for the SARS-CoV-2 spike protein. A lipid nanoparticle formulation delivers the mRNA into the recipient's cells. Once inside the cytoplasm of a cell, the mRNA provides instructions to the cell's protein production machinery to produce the trans-membrane spike protein antigen that becomes anchored on the cell's external surface. The mRNA does not enter the nucleus of the cell and does not interact with, or alter, human DNA. The immune system is engaged by both the transmembrane spike protein and immune receptors carrying spike antigens to induce humoral and cellular immune responses. The mRNA, lipid nanoparticle, and spike protein are degraded or excreted within days to weeks from time of immunization. mRNA vaccines are not live vaccines and cannot cause infection in the host.

Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

Non-replicating viral vector vaccines

COVID-19 vaccines based on viral vector platforms use a modified virus to carry genes that encode SARS-CoV-2 spike proteins into the host cells. The vector virus is a type of adenovirus that has been modified to carry COVID-19 genes and to prevent replication. These modifications are intended to prevent the viral vector from causing disease (i.e., they are non-replicating). Once inside the cell, the SARS-CoV-2 spike protein genes are transcribed into mRNA in the nucleus and translated into proteins in the cytosol of the cell. The AstraZeneca vaccine uses a modified chimpanzee adenovirus vector (ChAd). The Janssen vaccine uses a modified human adenovirus serotype 26 vector (Ad26).

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IV.1 Preparations of COVID-19 vaccines authorized and available for use in Canada

Table 2. COVID-19 vaccines available for use in Canada

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 / Covishield Vaccine	Janssen COVID-19 Vaccine
Type of vaccine	mRNA	mRNA	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)
Date of authorization in Canada	December 9, 2020	December 23, 2020	February 26, 2021	March 5, 2021
Authorized ages for use	16 years of age and older	18 years of age and older	18 years of age and older	18 years of age and older
Dose	0.3 mL (30 mcg of mRNA)[a]	0.5 mL (100 mcg of mRNA)	0.5 mL (5×10^{10} viral particles)	0.5 mL (5×10^{10} viral particles)
Authorized Schedule [b]	2 Doses, 3 weeks apart	2 Doses, 4 weeks apart	2 Doses, 4 to 12 weeks apart	1 Dose
Route of administration	IM	IM	IM	IM
Nature of the antigen	Transmembrane prefusion spike protein	Transmembrane prefusion spike protein	Transmembrane spike protein	Transmembrane prefusion spike protein
Adjuvant (if present)	None	None	None	None
Primary storage requirements pre-puncture[c]	-80°C to -60°C	-25°C to -15°C[d]	+2°C to +8°C	+2°C to +8°C
Additional storage options pre-puncture[c]	-25°C to -15°C for up to 2 weeks[e] OR 120 hours (5 days) at +2°C to +8°C AND/OR 2 hours up to +25°C	30 days at +2°C to +8°C AND/OR 12 hours at +8°C to +25°C	+2°C to +8°C	+2°C to +8°C
Diluent	Yes	No	No	No
Usage limit post-puncture	6 hours at +2°C to +25°C[f]	6 hours at +2°C to +25°C	6 hours at room temperature (up to +30°C) **or** 48 hours at +2°C to +8°C.	3 hours at room temperature (up to +25°C) **or** 6 hours at +2°C to +8°C
Formats available	Multi-dose vial (6 doses)[a], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (8-and 10-dose presentations), preservative-free	Multi-dose vial (5 doses), preservative-free

Abbreviations: ChAd: Chimpanzee adenovirus; Ad26: modified human adenovirus 26; IM: Intramuscular; mRNA: Messenger ribonucleic acid

[a] After dilution, one vial contains 6 doses of 0.3 mL each. However, vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in the product monograph supersedes the number of doses stated on vial labels and cartons. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.Refer to the product monograph available through Health Canada's Drug Product Database for choice of diluent, dilution instructions and type of syringes which can be used to extract 6 doses from a single vial.

[b] Authorized schedule per the product monograph. For NACI recommendations on intervals between doses, refer to Table 3.

[c] Protected from light during storage

[d] Do not store on dry ice or below -40°C

[e] Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

[f] After dilution, vaccine must be used within 6 hours

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IV.2 Efficacy and Effectiveness

Due to the availability of only short-term clinical trial data, the duration of protection provided by COVID-19 vaccination is currently unknown. However, studies are ongoing.

The following section highlights key efficacy and effectiveness data for authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and the authorized viral vector-based COVID-19 vaccines (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine) only. For additional details regarding trial design, including study population, length of follow-up, and efficacy for the authorized and available vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine).

Efficacy against symptomatic COVID-19 disease

The currently authorized mRNA COVID-19 vaccines have been shown to be highly efficacious in the short term against confirmed symptomatic COVID-19 disease (presence of one or more symptoms plus laboratory confirmation of SARS-CoV-2 infection) from one to two weeks after receiving the full two-dose series. The authorized mRNA vaccines are similarly efficacious in adults with one or more comorbidities, as well as in younger adults and older adults. However, evidence in adults of a much more advanced age (e.g., 85 years and older) and in long-term care facilities is limited.

In clinical trials, AstraZeneca COVID-19 viral vector vaccine has shown moderate short-term efficacy against symptomatic COVID-19 disease (presence of at least one pre-defined COVID-19 symptom plus laboratory confirmation of SARS-CoV-2 infection) in adults 18–64 years of age, at least two weeks after receiving the full series of two standard doses of the vaccine. Clinical trial data show that efficacy increased as the interval between doses increased. At present, there are insufficient clinical trial data in adults ≥65 years of age to assess vaccine efficacy in this age group. The vaccine is similarly efficacious in adults ≥18 years of age with and without pre-defined comorbidities (presence of one or more mild to moderate and controlled cardiovascular disease, respiratory disease, diabetes or obesity).In the initial absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized in Appendix C. These studies provide effectiveness estimates following the first dose of AstraZeneca vaccine and have shown a reduction in the risk of symptomatic disease and hospitalization that appears to reach a comparable level to that observed among persons of similar age who received one dose of mRNA vaccine.

The Janssen COVID-19 vaccine demonstrates moderate efficacy against symptomatic confirmed moderate to severe/critical COVID-19 infection from 14 days and 28 days post-vaccination, where the definition of moderate disease includes the presence of one to two or more of a relatively broad range of COVID-19 compatible signs and symptoms plus laboratory confirmation of SARS-CoV-2 infection. The point estimates of vaccine efficacy at these two time points across a variety of age groups are similar to the overall estimate, including among study participants ≥65 years of age who comprised approximately 20% of the study population. Point estimates of vaccine efficacy at 14 days post-vaccination are comparable in study participants with and without one or more comorbidities. In contrast, the point estimate of efficacy in participants with comorbidities is somewhat lower at 28 days post-vaccination. Efficacy for Janssen vaccine was based on clinical

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that were conducted in countries with widely circulating VOCs (South Africa and Brazil), which may have impacted its overall efficacy. This is in contrast to the clinical trials for other authorized COVID-19 vaccines.

The clinical trial data demonstrates that the authorized mRNA COVID-19 vaccines are efficacious over the short-term in individuals with or without evidence of prior SARS-CoV-2 infection. However, participants with laboratory-confirmed (using a nucleic acid amplification test, such as RT-PCR) SARS-CoV-2 infection prior to enrollment were excluded from the trials and the number of trial participants with evidence of previous infection (as defined by trial protocol) who had confirmed symptomatic COVID-19 disease during the trials were small; therefore, the efficacy in this population and how it compares to those without evidence of previous infection is unknown at this time. The efficacy of the Janssen COVID-19 vaccine in those with evidence of prior infection is inconclusive at this time due to small sample size, and this outcome has not been assessed for AstraZeneca COVID-19 vaccine.

The first dose of the authorized COVID-19 vaccines has been shown to offer at least short-term protection against confirmed COVID-19 disease. For mRNA vaccines, the highest efficacy is seen after the second dose is administered. There is currently no available evidence on medium- and long-term efficacy of the authorized COVID-19 vaccines, however trials are ongoing and this Statement will be updated as evidence emerges.

Efficacy and effectiveness against severe disease

The clinical trials of the authorized and available COVID-19 vaccines assessed efficacy against severe COVID-19 disease, but not all provided sufficient data to be able to assess the efficacy against hospitalizations or deaths.

The authorized mRNA and the Janssen COVID-19 vaccines appear efficacious against severe COVID-19 outcomes based on clinical trial data used for authorization (severe outcomes were defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death). However, the number of severe cases that have been observed to date was small in the Pfizer-BioNTech clinical trial and was too small in the AstraZeneca clinic trial to assess efficacy. Efficacy against hospitalization was not assessed in the clinical trials of the mRNA vaccines, but evidence from the clinical trials involving the viral vector vaccines is suggestive of a protective effect against hospitalization. To date there have been very few COVID-19 associated deaths identified in the clinical trials making it difficult to assess efficacy against this outcome. However, of the COVID-19 associated deaths identified in clinical trials, none have been in study participants receiving COVID-19 vaccines.

Emerging real world evidence from studies in the United Kingdom (UK) [6-8], Israel [9-11][12], the United States (US) [13], and Canada [14] suggests moderate to high vaccine effectiveness against severe COVID-19 outcomes after the first or second dose of mRNA COVID-19 vaccines,[6-11, 13, 14][12], and after the first dose of AstraZeneca COVID-19 vaccine, [6-8], including in older [6-8, 11] and frail [6] populations. COVID-19 related hospitalization was the most common severe COVID-19 outcome assessed, [6-9, 13][12], while fewer studies provided estimates of effectiveness against severe disease [9, 10] and death [7, 9, 14]. Emerging evidence from Israeli studies suggest high vaccine effectiveness after the second dose of Pfizer-BioNTech COVID-19 vaccine against severe disease, [9, 10] COVID-19 related hospitalization [9][12] and death [12]. Studies for COVID-19

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vaccines are ongoing and new effectiveness data against severe COVID-19 outcomes will be assessed as it emerges.

Efficacy and effectiveness against asymptomatic infection and transmission

Preliminary data from the ongoing Moderna COVID-19 vaccine trial showed a lower prevalence of SARS-CoV-2 positivity by PCR in asymptomatic participants at one particular time point (after Dose one but before Dose 2), and therefore viral shedding, in the group that received the vaccine compared to the placebo group. However, the current data are insufficient to draw conclusions. Exploratory analyses for the AstraZeneca viral vector vaccine has not demonstrated efficacy against confirmed SARS-CoV-2 asymptomatic infection, however the number of asymptomatic infections was small. The clinical trial of the Janssen COVID-19 vaccine found the vaccine to have moderate protection against asymptomatic and undetected COVID-19 infection. Studies are ongoing for these vaccines.

Evidence has begun to emerge from post-marketing studies conducted in Israel, [9] the UK, [15] and the US [16] on the effectiveness of COVID-19 vaccines against asymptomatic infection. Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose [9, 15] (depending on time since vaccination) and high after the second dose [9, 15]. Similar results were reported for mRNA COVID-19 vaccines in general (i.e., Moderna and Pfizer-BioNTech) [16]. In one UK study, asymptomatic SARS-CoV-2 infections were significantly less likely to be identified in vaccinated participants compared to those who were unvaccinated [15]. There are no results specific to other COVID-19 vaccines yet, but studies are ongoing.

Efficacy and effectiveness against variants

Evidence of varying protection and effectiveness offered by authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine) and viral vector-based COVID-19 vaccines (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine) against variants of SARS-CoV-2 is evolving. Please see Table 5 for a summary of this evidence.

The Janssen clinical trial was conducted during the time of emergence of SARS-CoV-2 VOC. As part of the testing conducted during the trial, a proportion of case isolates were genetically sequenced, and of the sequenced isolates, just over two-thirds of the isolates from Brazil were of the P.2 lineage and nearly all isolates from South Africa were of the B.1.351 lineage. Point estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset from 28 days post-vaccine are comparable to the overall estimate of efficacy against this outcome in Brazil and South Africa.

There is evidence that both the Pfizer and AstraZeneca vaccines protect against the B.1.1.7 SARS-CoV-2 variant first identified in the UK. There are also emerging data on the efficacy or effectiveness of mRNA vaccines against B.1.351. Evidence from the Janssen vaccine clinical trials indicate that it is protective against symptomatic moderate to severe/critical COVID-19 infection in areas where COVs B.1.351 and P.2 are circulating widely. The AstraZeneca clinical trial was conducted when the B.1.351 lineage was the predominant strain in South Africa, and vaccine efficacy was not demonstrated against this strain.

NACI will continue to monitor the evidence and update recommendations as needed.

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IV.3 Immunogenicity

No immunological correlate of protection has been determined for SARS-CoV-2; therefore, all immunological evidence in support of vaccine efficacy is indirect and cannot directly be used to estimate either vaccine efficacy or effectiveness.

There are several key knowledge gaps that affect the understanding of immune responses to COVID-19 vaccine:

- Which type of immune responses are important for protection from infection, severe disease, or transmission
- The durability of immune responses and how they may change over time
- How immune responses to natural infection compare to responses elicited from a vaccine
- How immune responses differ across populations (e.g., in immunocompromised, children) or by SARS-CoV-2 serostatus (i.e., past COVID-19 infection)
- How immune responses differ based on previous infection with non-SARS-CoV-2 coronaviruses

Due to limitations in the number of participants evaluated for immunogenicity outcomes and duration of follow up from COVID-19 clinical trial data, long-term evidence on immunogenicity is unknown. However, studies are ongoing.

The following section highlights key immunogenicity data for the authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine) and viral vector based COVID-19 vaccines (AstraZeneca COVID-19 vaccine and Janssen COVID-19 vaccine) only. For additional details regarding trial design, including study population and length of follow-up, and immunogenicity for these authorized vaccines, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine).

Humoral immune responses

All authorized COVID-19 vaccines induce humoral immune responses, including binding and neutralizing antibody responses. Humoral responses peaked after the second dose of mRNA vaccine, and after the second dose of AstraZeneca COVID-19 vaccine in participants who were not previously infected. Humoral immune responses were elevated after the one dose of Janssen vaccine. Some vaccines induce higher immune responses in younger populations.

Viral vector-based vaccines may induce anti-vector immune responses, which may impact future vaccine efficacy and effectiveness and may vary by age, dose, and interval between doses.

Cellular immune responses

All authorized, available COVID-19 vaccines have been shown to produce cellular immune responses. Cellular immune responses increased after the second dose of mRNA COVID-19 vaccine, while responses for AstraZeneca COVID-19 vaccine were maintained or decreased after the second dose. Cellular immune responses were present following one dose of Janssen vaccine.

Immunogenicity in individuals previously infected with SARS-CoV-2

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Immunogenicity data in previously infected individuals were available from five observational studies [17][18][19][20][21][22] including less than 100 participants. In all studies, individuals with previous SARS-CoV-2 infection had a significantly higher anti-spike and anti-RBD IgG concentrations, neutralizing titres and B and T cell reposes after dose 1, that were comparable to those observed in SARS-CoV-2 naïve individuals following the administration of the second vaccine dose. Elevated binding and neutralizing antibody responses were seen for both symptomatic and asymptomatic previously infected people compared to vaccine recipients who weren't previously infected. These findings were consistent with those reported by the RECOVER[22] study investigators. However, in the absence of an established correlate of protection, it is not possible to determine the significance of these findings as they relate to the level of protection against reinfection.

IV.4 Vaccine Administration

For additional vaccine product-specific information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Vaccine Administration Practices in the Canadian Immunization Guide (CIG), Part 1 - Key Immunization Information for additional general information.

As for the routine administration of all vaccines, COVID-19 vaccines should be administered in settings capable of managing anaphylaxis. Refer to Anaphylaxis and other Acute Reactions Following Vaccination in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

IV.4.1 Dose, route of administration, and schedule

Dose

Pfizer-BioNTech COVID-19 Vaccine

Each dose is 0.3 mL after dilution, containing 30 mcg of SARS-CoV-2 spike protein mRNA.

The dose for the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) is unique compared to that of most routine vaccinations. Special precaution should be taken to ensure the correct dose is taken from the multi-dose vial.

Moderna COVID-19 Vaccine

Each dose is 0.5 mL, containing 100 mcg of SARS-CoV-2 spike protein mRNA.

No dilution is required.

AstraZeneca COVID-19 Vaccine

Each dose is 0.5 mL, containing 5×10^{10} particles of SARS-CoV-2 spike protein.

No dilution is required.

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Janssen COVID-19 Vaccine

Each dose is 0.5 mL, containing 5×10^{10} particles of SARS-CoV-2 spike protein.

No dilution is required.

Route of administration

COVID-19 vaccines are given as an intramuscular (IM) injection into the deltoid muscle. The deltoid muscle of the arm is the preferred injection site in adolescents and adults (unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used).

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional general information.

Schedule

Refer to Table 3 for a summary of immunization schedules for authorized, available COVID-19 vaccines.

Table 3. Recommended immunization schedule, by COVID-19 vaccine

Vaccine product	Immunization schedule	Minimum interval	Authorized interval	Extended interval[a]
Pfizer-BioNTech COVID-19 vaccine	2-dose schedule	19 days[b]	21 days	16 weeks
Moderna COVID-19 vaccine	2-dose schedule	21 days[c]	28 days	16 weeks
AstraZeneca COVID-19 vaccine	2-dose schedule	28 days	4 to 12 weeks	16 weeks[d]
Janssen COVID-19 vaccine	1-dose schedule	N/A	N/A	N/A

[a] Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine up to four months after the first. NACI will continue to monitor the evidence and update this interval as needed.
[b] The basis for this minimum interval is that the per-protocol design for the Pfizer-BioNTech COVID-19 vaccine clinical trial was 19-23 days.
[c] The basis for this minimum interval is that the majority of participants in the Moderna COVID-19 vaccine clinical trial received the second dose 21 to 42 days after the first, as per the pre-defined window.
[d] The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.

Refer to Timing of Vaccine Administration in the CIG, Part 1 - Key Immunization Information for additional general information.

Extended intervals for COVID-19 vaccines to optimize early vaccine roll-out and population protection

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Currently, no data on medium- or long-term efficacy of COVID-19 vaccines are available. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series, as delays between doses do not result in a reduction in final antibody concentrations for most multi-dose (prime-boost) products. For many other multi-dose vaccines provided in adulthood using other vaccine technologies, the greatest proportion of short-term protection is achieved with the first dose with additional doses primarily intended to extend protection over the longer term. However, the follow-up time in COVID-19 vaccine clinical trials is short, the duration of protection after one or both doses is unknown, and mRNA and viral vector-based vaccines represent relatively new vaccine technologies.

Morbidity and mortality from COVID-19 is ongoing. Extending the interval to the second dose of a COVID-19 vaccine maximizes vaccine supply to immunize the largest number of people as quickly as possible. Principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. Please refer to the NACI Advisory Committee Statement: Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada in the context of limited vaccine supply for a summary of the evidence.

Follow-up of vaccine effectiveness in individuals for whom the second dose is delayed or who have otherwise missed their second dose (e.g., missed a follow-up immunization appointment) will be important to inform future recommendations and ensure completion of the vaccine series as soon as possible. NACI will continue to monitor the evidence and update recommendations as needed.

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IV.4.2 Booster doses and re-immunization

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete. Given the emergence of VOC against which vaccine effectiveness may be decreased, additional vaccine doses may be necessary. NACI will continue to monitor the evidence and update recommendations as needed.

IV.4.3 Interchangeability

NACI recommends that the vaccine series be completed with the same COVID-19 vaccine product.

Currently, no data exist on the interchangeability of COVID-19 mRNA vaccines. However, the spike proteins encoded by either of the authorized mRNA vaccines are stabilized in the same manner to remain in the pre-fusion conformation, though other vaccine components like the lipid nanoparticle and the mRNA sequence may be different. Currently, no data exist on the interchangeability of the AstraZeneca COVID-19 vaccine with other COVID-19 vaccines.

Similarly, no data exists on the interchangeability of COVID-19 viral vector vaccines. The authorized viral vector vaccines differ in three key ways: number of doses in a complete series, SARS-CoV-2 antigen, and virus used as the vector. The AstraZeneca vaccine is a two-dose vaccine based on ChAd that encodes a wild-type, unstabilized spike protein. The Janssen vaccine is a one-dose vaccine based on Ad26 that encodes a spike protein stabilized in the prefusion conformation.

If the vaccine product used for a previously received dose is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g., complete a series started with an mRNA vaccine with another mRNA vaccine). In the context of limited COVID-19 vaccine supply and the absence of evidence on interchangeability of COVID-19 vaccines, the previous dose may be counted, and the series need not be restarted. In the event that an individual receives one dose of the AstraZeneca vaccine and is unable to receive the same type of viral vector vaccine for the second dose, receiving the Janssen vaccine would be considered as restarting a vaccine series, as one dose of the Janssen vaccine is considered to be a complete series. There is limited evidence that two heterologous COVID-19 viral vector vaccines can be used in the same series [23].

At this time, it is not recommended that vaccines of different types (e.g., mRNA vaccine and viral vector vaccine) be used in the same series, however, studies involving mixed schedules with different vaccines are ongoing. Recommendations on which vaccine product to complete a vaccine series in individuals who have received one dose of the AstraZeneca COVID-19 vaccine will be made immediately after evidence on mixed COVID-19 vaccine schedules is available (expected June 2021). Active surveillance of effectiveness and safety of a mixed schedule are important and these recommendations may change as further evidence becomes available. Accurate recording of vaccines received will be critical. NACI will continue to monitor the evidence and update recommendations as needed.

Refer to Principles of Vaccine Interchangeability in the CIG, Part 1 - Key Immunization Information for additional general information.

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IV.4.4 Post-vaccination counseling

NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.

Analgesics and antipyretics were used in clinical trials of COVID-19 vaccine for the management of pain and/or fever after vaccination. There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.

All vaccine recipients should be instructed to seek medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the immunization clinic/venue.

All vaccine recipients who develop symptoms compatible with COVID-19 should be tested for SARS-CoV-2 to document breakthrough illness, particularly in the context of the emergence of VOC. Genetic sequencing should be strongly considered for those with SARS-CoV-2 infection after vaccination with either one or two doses of a COVID-19 vaccine.

Anyone receiving the AstraZeneca COVID-19 vaccine should be informed of the recently recognized adverse event of VITT and advised to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 28 following receipt of the AstraZeneca vaccine (although most occur between days 4 and 14 post-vaccine) [24]. Symptoms to be vigilant for include: shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including sudden onset of severe or persistent worsening headaches or blurred vision, skin bruising (other than at the site of vaccination) or petechiae. In addition, healthcare professionals should be aware of VITT including how to diagnose and treat the condition (see Ontario Science Table guidelines).

Refer to Vaccine Administration Practices in the CIG, Part 1 - Key Immunization Information for additional information on pre- and post-vaccination counseling.

IV.5 Serological testing

Serologic testing is not needed before or after immunization with COVID-19 vaccine.

IV.6 Storage requirements

Pfizer-BioNTech COVID-19 vaccine

Frozen vials prior to use
The Pfizer-BioNTech COVID-19 vaccine must be stored at ultra-low temperatures of -80°C to -60°C and protected from light, in the original packaging, until ready to use.

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Refer to the re-icing guidelines (available at CVDVaccine.ca) for instructions regarding the use of the manufacturer's original thermal container for temporary storage.

Vials may also be stored at -25°C to -15°C for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

Thawed, unpunctured vials (prior to dilution)
The Pfizer-BioNTech COVID-19 vaccine may be thawed and stored at +2°C to +8°C for up to 120 hours (5 days) or at room temperature (up to +25°C) for no more than 2 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

Do not refreeze thawed vials.

Thawed, punctured vials (after dilution)
The Pfizer-BioNTech COVID-19 vaccine must be stored between +2°C to +25°C and used within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.

Moderna COVID-19 vaccine

Frozen vials prior to use
The Moderna COVID-19 vaccine should be stored at temperatures of -25°C to -15°C and protected from light in the original packaging. Do not store on dry ice or below -40°C.

Thawed, unpunctured vials
If not punctured, the Moderna COVID-19 vaccine can be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 12 hours.

Do not refreeze thawed vials.

Thawed, punctured vials
The Moderna COVID-19 vaccine can be stored between +2°C to below +25°C but must be discarded after 6 hours from the time of first puncture.

AstraZeneca COVID-19 vaccine

Unopened multidose vial
The AstraZeneca vaccine can be stored between +2°C to +8°C and protected from light in the original packaging. Do not freeze.

Opened multidose vial
After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (up to

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+30°C) or 48 hours in a refrigerator (+2°C to +8°C).

After the first puncture, the vial can be re-refrigerated, but the cumulative storage time at room temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours. After this time, the vial must be discarded.

Janssen COVID-19 vaccine

Unopened multidose vial
The Janssen COVID-19 vaccine can be stored between +2°C to +8°C and protected from light in the original packaging. Do not freeze.

Punctured multidose vial
After the first dose has been withdrawn, the vial/filled syringe can be held at 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours, after the first puncturing of the vial. Discard if vaccine is not used within this time.

For more information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

IV.7 Simultaneous administration with other vaccines

NACI recommends that COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated).

Currently, no data exist on the simultaneous administration of COVID-19 vaccine with other vaccines. In the absence of evidence, attempts should be made to avoid simultaneous administration to maximize benefits of COVID-19 vaccination while minimizing any risks of harm, including the potential for immune interference or the erroneous attribution of an adverse event following immunization (AEFI) to a particular vaccine. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

In the absence of evidence, it would be prudent to wait for a period of at least 28 days after each vaccine dose of an mRNA or viral vector COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. It would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to a particular vaccine.

Refer to Timing of Vaccine Administration in the CIG, Part 1 – Key Immunization Information for additional general information on simultaneous administration of other vaccines.

IV.8 Vaccine safety and adverse events following immunization (AEFI)

Due to limitations in the number of participants and duration of follow-up from COVID-19 clinical trials, medium- and long-term evidence on vaccine safety is limited. However post-licensure vaccine pharmacovigilance is ongoing and safety signals around the world are detected and

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communicated globally. Clinical trials of the authorized COVID-19 vaccines excluded individuals with a history of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. However, studies are ongoing.

The following section highlights key safety and AEFI data for the authorized COVID-19 vaccines. For additional details regarding trial design, including study population and length of follow-up, and safety for the vaccines authorized and available for use in Canada, refer to the evidence summaries in Appendix A (for the Pfizer-BioNTech COVID-19 vaccine), Appendix B (for the Moderna COVID-19 vaccine), Appendix C (for the AstraZeneca COVID-19 vaccine) and Appendix D (for the Janssen COVID-19 vaccine). Refer to Appendix E for a summary of the frequency of AEFI for the different COVID-19 vaccine products.

Refer to Part 2 - Vaccine Safety in the CIG for definitions of AEFIs and additional general information.

IV.8.1 Very common and common adverse events

Common adverse events are defined as those that occur in 1% to less than 10% of vaccine recipients; very common adverse events occur in 10% or more of vaccine recipients. Please see Appendix E for a summary of adverse events identified in clinical trials of authorized, available COVID-19 vaccines.

Local

Pain at the injection site is very common after administration of the currently authorized COVID-19 vaccines. More than 40% of recipients experienced injection site pain. Redness and swelling are common or very common after administration. Localized axillary swelling and tenderness was a solicited adverse event in the Moderna COVID-19 clinical trial and was very common after administration with that vaccine. Local adverse events are usually mild or moderate and resolve within a few days of vaccination. For the authorized mRNA COVID-19 vaccines, pain at the injection site was slightly more frequent in younger adults compared to older adults. For AstraZeneca COVID-19 vaccine, local reactions were milder and reported less frequently after the second vaccine dose in all age groups. Similar frequencies of local reactions were reported across age groups after administration of the Janssen vaccine.

Systemic

Fatigue, headache, muscle pain, chills, and joint pain are all either common or very common after the administration of the currently authorizedCOVID-19 vaccines. Fever was very common after administration of the second dose of the mRNA COVID-19 vaccines and common after any dose of viral vector vaccines. More than a quarter of vaccine recipients experienced headache and/or fatigue after any dose. Systemic adverse events are usually mild or moderate intensity and resolve within a few days of vaccination. For the mRNA COVID-19 vaccines, systemic reactions are more frequent after the second vaccine dose and in younger adults. For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose than the first in all age groups. Similar frequencies of local reactions were reported across age groups after administration of the Janssen vaccine.

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Adverse events following the second dose of COVID-19 in individuals previously infected with SARS-CoV-2

Evidence on the safety of vaccine booster doses is available from observational[25] and clinical studies[18][26][27]. Occurrence of solicited and unsolicited systemic adverse events in individuals with prior SARS-CoV-2 infection was slightly higher compared to the SARS-CoV-2 naïve population, primarily in younger adults. However, there was no observed increase in the frequency of more severe adverse events in this population. Two observational studies included less than 100 patients with persistent symptoms from prior COVID-19 infections (Long COVID). In this subgroup, receipt of COVID-19 vaccination with either an mRNA or viral vector vaccine was not associated with a worsening of Longl COVID symptoms or increased reactogenicity following immunization.

IV.8.2 Uncommon, rare, and very rare adverse events

Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. The probability of detection of very rare adverse events in clinical trials is low given clinical trial population sizes; therefore, ongoing pharmacovigilance is essential.

To date, the available data does not indicate that vaccination of SARS-CoV-2 naïve individuals with authorized COVID-19 vaccines will elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 (e.g., vaccine-enhanced disease); however, further study is needed.

Lymphadenopathy was a solicited event in the Moderna clinical trials but not in other authorized COVID-19 vaccine trials see Appendix E). It was uncommonly reported after administration of the Pfizer-BioNTech, AstraZeneca and Janssen COVID-19 vaccines.

No other solicited uncommon, rare, or very rare adverse events were reported among vaccinated participants in the clinical trials at this time.

Thrombosis with Thrombocytopenia following Vaccination with viral vector COVID-19 vaccines

Very rare cases of serious blood clots (at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis) associated with thrombocytopenia have been reported globally following vaccination with viral vector COVID-19 vaccines. The terminology for this syndrome has been evolving since the safety signal was detected. It has been referred to as Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT), Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), and would be classified as the anti-PF4 positive subgroup within the case definition for Thrombosis with Thrombocytopenia Syndrome (TTS).

The exact mechanism by which the viral vector COVID-19 vaccines may trigger this syndrome is still under investigation but the mechanism appears to be similar to spontaneous heparin-induced thrombosis (HIT) / autoimmune heparin-induced thrombosis, where antibodies to platelet factor 4 (PF4)-polyanion complexes induce platelet activation, which causes thrombosis and

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thrombocytopenia. Due to the immune stimulus, and frequent occurrence of disseminated intravascular coagulation, clots related to VITT can be very aggressive and challenging to treat. They cannot be managed the same way as clots related to oral contraceptives, immobility, or long haul flights, and have an entirely different mechanism of action. While thrombotic events have been rarely reported after vaccination with mRNA COVID-19 vaccines or after infection with SARS-CoV-2, most of these events have not been accompanied by thrombocytopenia or the other distinctive characteristics of VITT.

Cases of VITT usually occur between 4 and 28 days after receipt of a viral vector COVID-19 vaccine. Due to the time to onset of symptoms and diagnosis, as well as the variability in reporting, the rate of this adverse event is uncertain. The rate of VITT is estimated to be between 1 per 100,000 and 1 per 250,000 persons vaccinated with the AstraZeneca COVID-19 vaccine. This rate is evolving as cases continue to be reported and investigated, and varies between countries. The rate of VITT in Canada as of April 28, 2021 is closer to 1 per 100,000 persons vaccinated with the AstraZeneca/Covishield COVID-19 vaccine. The case fatality rate of VITT also varies between countries, and ranges between 20 and 40%. Many cases have been reported to have serious long-term morbidity, including neurologic injury. Reports of adverse events that closely resemble VITT after administration of the Janssen vaccine are emerging from the United States. As of April 28, 2021, 17 cases have been confirmed after 8 million doses of Janssen vaccine administered in the United States, and others are under investigation. For more information, see Appendix C, Appendix D, Appendix F, and NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.

IV.8.3 Guidance on reporting adverse events following immunization (AEFI)

Vaccine providers are asked to report AEFIs through local public health departments and to follow AEFI reporting requirements that are specific to their province or territory. In general, any serious (defined as resulting in hospitalization, permanent disability or death) or unexpected adverse event that is temporally related to vaccination should be reported.

In addition to provincial or territorial reporting requirements, the Brighton Collaboration has developed a list of Adverse Events of Special Interest (AESI) that are of particular interest and should be reported. Refer to https://brightoncollaboration.us/covid-19/ for the list with definitions.

There may be additional very rare AEFIs that have not been detected through clinical trials to date.

Refer to Adverse Events Following Immunization (AEFI) in the CIG, Part 2 – Vaccine Safety for additional information on definitions, reporting, investigating and managing, and causality assessments for AEFIs.

Refer to Reporting Adverse Events Following Immunization (AEFI) in Canada for additional information on the completion and submission of AEFI reports.

Refer to the AEFI weekly report for more information on the reported adverse events following COVID-19 vaccination in Canada.

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IV.9 Contraindications and Precautions

Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines.

Table 4 lists potential non-medicinal ingredients in authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products. These reactions have occurred rarely, and ranged from mild cutaneous reactions to anaphylaxis. Anaphylaxis is typically a rare, severe, life-threatening allergic reaction usually with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include, but are not limited to: generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock. It is important to note that other, less serious reactions may mimic allergic reactions (e.g., vasovagal syncope) and vaccination is not contraindicated in these cases.

Refer to Anaphylaxis and other Acute Reactions Following Vaccination in the CIG, Part 2 – Vaccine Safety for information on the management of anaphylaxis post-vaccination.

Table 4. Ingredients of authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products

Vaccine product	Potential allergen included in the vaccine or its container	Other products where the potential allergen may be found*
Pfizer-BioNTech COVID-19 vaccine	polyethylene glycol (PEG) [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel[d].
Moderna COVID-19 vaccine	PEG [a,b,c]	Over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel[d].
	tromethamine[e] (trometamol or Tris)	Component in contrast media, oral and parenteral medications.
AstraZeneca COVID-19 vaccine	polysorbate 80[c]	medical preparations (e.g., vitamin oils, tablets, and anticancer agents), cosmetics[d,f]
Janssen COVID-19 vaccine	polysorbate 80[c]	medical preparations (e.g., vitamin oils, tablets, and anticancer agents), cosmetics[d,f]

N.B. This is not a complete list of products.

[a] Medications that contain PEG are described in Stone CA, et al., DOI:10.1016/j.jaip.2018.12.003

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[b] A review of immediate type hypersensitivity reactions to PEG is available in Wenande et al, DOI: 10.1111/cea.12760
[c] There is a potential of cross-reactive hypersensitivity between PEG and polysorbates
[d] PEG is an additive in some food and drinks but allergic reactions to PEG in food or drinks have not been documented.
[e] One case report of anaphylaxis to tromethamine has been described (Lukawska et al, DOI: 10.1016/j.jaip.2018.08.035).
[f] Case reports of anaphylaxis to polysorbate 80 have been described (Badiu et al, DOI: 10.1136/bcr.02.2012.5797, Palacios Castaño et al, DOI: 10.18176/jiaci.0109).

Rare cases of VITT have been reported following immunization with viral vector COVID-19 vaccines. Investigations are ongoing and the recommendations will be updated as evidence becomes available. For more information, refer to Appendix C, Appendix D, and NACI rapid response: Recommended use of AstraZeneca COVID-19 vaccine in younger adults.

Contraindications

Anaphylaxis and Allergies to a COVID-19 vaccine

An authorized COVID-19 vaccine should not be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector). If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided, an authorized COVID-19 vaccine using a different platform may be considered for re-immunization (i.e., individuals with anaphylaxis post mRNA vaccine may be offered a viral vector vaccine and individuals with anaphylaxis post viral vector vaccine may be offered a mRNA vaccine). If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization.

An authorized COVID-19 vaccine should not be routinely offered to individuals who are allergic to any component of the specific COVID-19 vaccine or its container. For a comprehensive list of components in each authorized COVID-19 vaccine and its container, please consult the corresponding product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.

Thrombosis and Thrombocytopenia following vaccination

Patients who have experienced major venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 COVID-19 vaccine.

Precautions

Hypersensitivity and Allergies

If a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided; vaccination may be considered in individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) after a previous dose of authorized COVID-19 vaccines or any of its components. Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, if vaccination is

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chosen, an extended period of observation post-vaccination of at least 30 minutes should be provided for the aforementioned individuals.

Individuals with proven severe allergic reaction (e.g., anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated and do not need to be assessed. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of the vaccine. Therefore, an extended period of observation post-vaccination of 30 minutes should be provided for the aforementioned individuals.

Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.

Acute illness

Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from SARS-CoV-2 infection to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any persons are identified with symptoms on arrival at the venue, they should be instructed to follow current local public health measures.

As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, one should wait until all symptoms of an acute illness are resolved before vaccinating with an authorized COVID-19 vaccine.

Pregnancy

The safety and efficacy of authorized COVID-19 vaccines in pregnancy have not yet been established, however safety data are accumulating from post marketing surveillance. Pregnant individuals were excluded from the mRNA and viral vector COVID-19 vaccine clinical trials. Currently, there are limited data on the safety of COVID-19 vaccines from animal developmental and reproductive toxicity studies. In rats that received the Moderna COVID-19 vaccine prior to or during gestation, no safety concerns regarding female reproduction, fetal/embryonal development, or postnatal development were demonstrated. According to a report presented to the European Medicines Agency (EMA), studies in rats using four full doses of the Pfizer-BioNTech COVID-19 vaccine did not indicate adverse effects with respect to fertility, pregnancy, embryo/fetal development, or postnatal development, up to day 21. Developmental and Reproductive Toxicity (DART) animal studies for the AstraZeneca COVID-19 vaccine are ongoing. A US Food and Drug Administration (FDA) review of a study in rabbits that received the

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Janssen COVID-19 vaccine at two times the human dose prior to or during gestation concluded there were no adverse effects on female reproduction, fetal/embryonal development, or postnatal development.

Hematologic

In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.

Thrombosis and Thrombocytopenia

Individuals who have experienced a previous CVST with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered.

Anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risk of VITT and advised to seek immediate medical attention if they develop symptoms of VITT. These symptoms may include: shortness of breath, chest pain, leg swelling or pain, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms after vaccination including sudden onset of severe headaches, persistent or worsening headaches, blurred vision, confusion or seizures, or who experiences unusual skin bruising or petechiae beyond the site of vaccination after a few days, should seek prompt medical attention.

Refer to Contraindications and Precautions in the CIG, Part 2 - Vaccine Safety for additional general information.

IV.10 Drug Interactions

There have been no drug interactions studies performed to date.

For more information about potential interactions with products containing anti-SARS-CoV-2 antibodies, refer to section IV.11 Blood products, human immunoglobulin and timing of immunization, in this Statement.

Tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)
There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed.

In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent in order to avoid missing cases due to potentially false-negative results.

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IV.11 Blood Products, Human Immunoglobulin and Timing of Immunization

NACI recommends that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

To date, there is insufficient evidence on the receipt of both a COVID-19 vaccine and anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention. Therefore, timing of administration and potential interference between these two products are currently unknown. Administration of these products close together may result in decreased effectiveness of a COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies because the monoclonal antibodies have high affinity for the spike protein expressed by the vaccines, which could prevent the production of antibodies stimulated by the vaccine.

In the post-exposure setting, expert clinical opinion should be sought on a case-by-case basis when deciding whether anti-SARS-CoV-2 monoclonal antibodies would be appropriate to administer after receipt of COVID-19 vaccine, taking into consideration the risk of exposure and the risk of severe COVID-19 disease in the individual.

To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

V. RECOMMENDATIONS

Following the thorough review of available evidence summarized above, as well as the systematic assessment of ethics, equity, feasibility and acceptability considerations with the EEFA Framework [2] as summarized in NACI's Guidance on Key Populations for Early COVID-19 Immunization, NACI makes the following evidence-informed recommendations for public health program level decision-making for the effective and equitable use of COVID-19 vaccines authorized and available for use in Canada.

NACI will continue to carefully monitor the scientific developments related to COVID-19 and COVID-19 vaccines, as well as ongoing vaccine pharmacovigilance, and will update recommendations as required.

Please note:

- A *strong recommendation* applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.
- A *discretionary recommendation* may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

Please see Table 6 for a more detailed explanation of the strength of NACI recommendations.

RECOMMENDATIONS ON AUTHORIZED, AVAILABLE COVID-19 VACCINES

These recommendations apply only to COVID-19 vaccines currently authorized for use in Canada (Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine; AstraZeneca COVID-19

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vaccine; and Janssen COVID-19 vaccine). In considering these recommendations and for the purposes of publicly funded program implementation, provinces and territories may consider local programmatic factors (e.g., logistical and operational contexts, resources) and local epidemiology (e.g., transmission of SARS-CoV-2 VOC).

1. **NACI preferentially recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered.**
   (Strong NACI Recommendation)

2. **NACI recommends that a complete series with a viral vector COVID-19 vaccine may be offered to individuals 30 years of age and older without contraindications, only if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine AND all of the following conditions apply:**
   a) The benefit-risk analysis* determines that the benefit of earlier vaccination with the viral vector COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
   b) The benefits, relative risk* and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND
   c) There will be substantial delay to receive an mRNA vaccine.

   Note: Provinces and territories should adapt the age limit based on their local epidemiology.

   (Discretionary NACI Recommendation)

*See Risk Assessment Tool below and Management Options Table (Section V.I) to assist with this determination

***Risk Assessment Tool for the use of viral vector COVID-19 vaccines**

The benefit-risk analysis for vaccination with a viral vector COVID-19 vaccine while an authorized mRNA COVID-19 vaccine is temporarily unavailable or inaccessible may vary between jurisdictions and individuals and will depend on various factors, summarized in the table below.

Factors that may vary between jurisdictions and individuals	Considerations[1]
Local COVID-19 epidemic conditions	• The benefit of viral vector COVID-19 vaccines increases in regions of moderate, high or very high epidemic transmission or in regions with increasing incidence rates, where immediate protection is needed to prevent symptomatic disease and preserve health system capacity. • Consider local transmission potential for viral variants of concern and anticipated protection against them.
Local vaccine supply	• Consider how long an individual will need to wait to be offered an mRNA vaccine, based on expected vaccine supply and priority group.

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Risk of severe illness and death	• Consider offering available viral vector COVID-19 vaccines to individuals at risk of severe illness and death who do not wish to wait to receive mRNA vaccine. • The risk of severe outcomes of COVID-19 decreases as age decreases.
Risk of exposure	• Consider offering available viral vector COVID-19 vaccines to individuals at increased risk of exposure to SARS-CoV-2 due to inability to physically distance or reduced access to infection prevention and control measures who do not wish to wait to receive an mRNA vaccine.
Logistical considerations	• Although the viral vector COVID-19 vaccines are refrigerator-stable, which makes these vaccines easier to store and handle, infrastructure now exists to support the use of ultra-frozen and frozen mRNA vaccines. • The Janssen COVID-19 vaccine is authorized as a single dose; however, the duration of protection of one dose is unknown.
Risk of VITT	• The rate of this adverse event is estimated to be between 1/100,000 and 1/250,000 persons vaccinated with the AstraZeneca COVID-19 vaccine, however this rate is evolving as cases continue to be reported and investigated. The estimate in Canada as of April 28, 2021 is closer to 1/100,000. The case fatality rate typically ranges between 20 and 40%. Other predisposing factors for VITT are unclear. • Evidence of this adverse event after vaccination with the Janssen COVID-19 vaccine is emerging in the United States. As of April 28, 2021, 17 cases have been confirmed after 8 million doses of the Janssen vaccine administered. Most of these cases were in female between 18 and 59 years of age, however additional cases are under investigation. Initial cases of VITT after vaccination with AstraZeneca COVID-19 vaccine were also seen in younger females; however, reports of VITT in older adults and in males have more recently been confirmed. The risk of developing VITT after receipt of the AstraZeneca COVID-19 vaccine does not seem to be related to age or sex.
Vaccine characteristics	• Emerging data suggests that all authorized COVID-19 vaccines offer protection against hospitalization and likely also death from COVID-19. • Results from clinical trials of mRNA vaccines suggest superior efficacy against symptomatic COVID-19 disease compared to the viral vector vaccines. • There is evidence that both the Pfizer-BioNTech and AstraZeneca vaccines protect against the B.1.1.7 SARS-CoV-2 variant. In studies in South Africa, the Janssen vaccine was shown to offer protection against the B.1.351 SARS-CoV-2 variant, while the AstraZeneca vaccine was shown not to offer protection against that variant of concern. In studies in Brazil, the Janssen vaccine was shown to offer protection against the P.2 variant. • Early evidence suggests that the Pfizer-BioNTech vaccine has moderate to high effectiveness against asymptomatic infection, with some evidence of protection available for Moderna and

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	Janssen as well. Early evidence suggests that the AstraZeneca vaccine may not be efficacious against asymptomatic infections.
Access to diagnosis and treatment for COVID-19 and VITT	• Consider healthcare system capacity, access to tertiary and ICU care, as well as IVIG for treatment of VITT.
Risk of exacerbating inequities	• The use of viral vector COVID-19 vaccines may increase inequities for individuals with limited ability to reduce their personal risk of infection or who work in occupations with direct close physical contact with the public, and due to the complexities of making an informed choice with regard to the risk and benefits of earlier vaccination with the viral vector COVID-19 vaccines. • Consider the impact of exacerbating inequities in these populations, many of whom belong to marginalized and disadvantaged groups disproportionately affected by the pandemic.

[1] NACI is monitoring evolving evidence

Refer to the Management Options Table for COVID-19 vaccines authorized and available for use in Canada (Section V.I) for a summary of evidence and factors for jurisdictions to consider when implementing COVID-19 immunization programs.

Summary of evidence and rationale:

- The COVID-19 pandemic has caused significant morbidity and mortality, as well as social and economic disruption. The COVID-19 immunization program should be rolled out as efficiently, effectively and equitably as possible.
- mRNA COVID-19 vaccines are authorized in individuals 16 years of age and older (Pfizer-BioNTech COVID-19 vaccine) and in individuals 18 years of age and older (Moderna COVID-19 vaccine). Non-replicating viral vector vaccines are authorized for use in Canada for individuals 18 years of age and older (AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine).
- A complete series for all currently authorized and available COVID-19 vaccines is two doses except for the Janssen COVID-19 vaccine which is authorized as a single dose.
- See Table 1 for risk factors associated with increased risk of severe outcomes from COVID-19 and increased risk of exposure to COVID-19. Please refer to NACI's Guidance on the prioritization of key populations for COVID-19 immunization for additional details on sequencing of key populations, including a comprehensive analysis of ethical, equity, feasibility and acceptability considerations.

mRNA COVID-19 vaccines

- Clinical trial data available to date have shown that the currently authorized mRNA COVID-19 vaccines are highly efficacious (94 to 95%) in preventing confirmed symptomatic COVID-19 disease in the short term, starting at one to two weeks after receiving the full two-dose series.
- Highest efficacy and maximum immune response were observed after the second dose. Efficacy of a two-dose series was consistent across age groups.
- Estimates of vaccine effectiveness of the Pfizer-BioNTech vaccine were comparable in countries where the predominant circulating strain was the B.1.1.7 VOC first identified in the UK.

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- Local and systemic adverse events were generally less frequent in older adults (≥56 in the Pfizer-BioNTech clinical trial and ≥65 in the Moderna clinical trial).
- The authorized mRNA vaccines are similarly safe and efficacious in those with one or more comorbidities (e.g., body mass index ≥30 kg/m^2, chronic pulmonary disease, diabetes mellitus, cardiac disease).

AstraZeneca COVID-19 vaccine

- Combined evidence from clinical trial and observational study data available to date have shown that the AstraZeneca COVID-19 vaccine offers protection against symptomatic COVID-19 disease and hospitalization in adults ≥18 years of age after receiving at least one dose.
  - Clinical trial data available to date have shown that the AstraZeneca COVID-19 vaccine has demonstrated moderate efficacy against symptomatic, confirmed COVID-19 of approximately 62% in those 18-64 years of age. Efficacy of a two-dose series increased to approximately 82% when the interval between doses was 12 weeks or more. In adults 65 years of age and over, observational data from the UK of vaccine effectiveness after one dose have shown a reduction in the risk of symptomatic disease and hospitalization.
  - The highest efficacy with the authorized regimen of AstraZeneca COVID-19 vaccine was seen in clinical trial groups that had a longer interval between doses. Clinical trials suggest that vaccine efficacy increases with extended intervals between the first and second dose of vaccine, with a maximum reduction in risk of symptomatic disease observed at 12 weeks or more following the priming dose.
- Data suggest AstraZeneca COVID-19 vaccine has a vaccine efficacy of 74.6% against the B.1.1.7 VOC first identified in the UK (compared to 84.1% against the non-B.1.1.7 strain). Published data suggests a vaccine efficacy of 10.4% against mild to moderate illness from the B.1.351 VOC first detected in South Africa.
- In clinical trials, the majority of local and systemic adverse events with the AstraZeneca COVID-19 vaccine were mild and transient and did not differ by dose administered or age.
- Rare but serious cases of blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported globally following post-licensure use of AstraZeneca COVID-19 vaccine, usually between 4 and 28 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The exact mechanism by which the AstraZeneca COVID-19 vaccine may trigger VITT is still under investigation. The case fatality rate typically ranges between 20 and 40%.
- AstraZeneca COVID-19 vaccine is similarly efficacious in those with one or more mild to moderate and controlled medical conditions (e.g., cardiovascular disease, respiratory disease, diabetes, body mass index ≥30 kg/m2).

Janssen COVID-19 vaccine

- Clinical trial data available to date have shown that the Janssen COVID-19 vaccine is 67% efficacious against moderate to severe/critical symptomatic COVID-19 disease at least two weeks after receiving one dose.
- Efficacy was consistent across age groups.
- Point estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection from 28 days post-vaccination were comparable in the trial conducted in Brazil (68%), where two-thirds of the isolates were of the P.2 lineage

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and in the one conducted in South Africa (64%), where almost all isolates were of the B.1.351 lineage.
- Local and systemic adverse events were typically mild and transient, and no safety signals were detected in clinical trials.
- One case of cerebral venous thrombosis was reported in a 25-year-old male among the 21,895 vaccine recipients in the Janssen clinical trial. At the time, the event was deemed unrelated to the vaccine as there were other possible contributing factors but has now been confirmed to be VITT. As of April 28, 2021, 17 cases of VITT have been confirmed after 8 million doses of Janssen vaccine administered in the United States. Investigations are ongoing.
- The vaccine is similarly safe and efficacious in those with one or more comorbidities 14 days after vaccination, although efficacy is somewhat lower in participants with comorbidities at 28 days post-vaccination.

mRNA COVID-19 vaccines versus viral vector COVID-19 vaccines

NACI reviewed the recent epidemiology of COVID-19 in Canada (including circulation of variants), vaccine characteristics (including efficacy, effectiveness, safety), evidence and international guidance on VITT, anticipated vaccine supplies, Health Canada's assessment of COVID-19 vaccines, as well as a comprehensive analysis of the implications on ethics, equity, feasibility and acceptability [2] of its recommendations for the use of COVID-19 vaccines in Canada. NACI assessed the risk of being admitted to the ICU and dying from VITT, if one had to wait for an mRNA vaccine given Canada's expected vaccine supply, compared to COVID-19 ICU admissions and deaths that could be prevented by an early dose of the AstraZeneca or Janssen COVID-19 vaccines, by age across various COVID-19 epidemiologic scenarios (very low, low, moderate, high, very high activity). Please see Appendix F for details and limitations. Given the low numbers of events reported for VITT, there is a high level of uncertainty in the incidence of this adverse event by age group. Initial data suggested there may be a trend for increasing incidence of VITT with decreasing age, but this could be due to differences in reporting and vaccination with viral vector COVID-19 vaccines in different age groups. While the epidemiology of COVID-19 may evolve with the circulation of VOCs, evidence to date reveals the risk of severe disease associated with COVID-19 increases with age, with younger adults at lower risk of hospitalization and death. NACI will continue to monitor the epidemiology of COVID-19 and reassess these recommendations as mRNA COVID-19 vaccine supply increases.

Upon analysis of the information available, NACI concluded that given an expected increase in mRNA vaccine supplies and their associated timelines, the differences in the epidemiology and risk of COVID-19 across Canada and between populations, and because of the evolving evidence for VITT, there is uncertainty in the evidence of advantages and disadvantages of the use of viral vector COVID-19 vaccines in vaccine programs for all Canadians. Therefore, NACI made a discretionary recommendation on the use of viral vector COVID-19 vaccines for individuals 30 years of age and older who prefer an earlier vaccine rather than wait for an mRNA vaccine, only if certain conditions are met (including a benefit-risk analysis, informed consent, and substantial delay for receipt of an mRNA vaccine). NACI summarized various factors (in addition to age) to consider to facilitate a benefit-risk analysis in its Risk Assessment Tool for the use of viral vector COVID-19 vaccines.

As demonstrated in Appendix F, the rate of ICU admission from COVID-19 potentially prevented by a viral vector COVID-19 vaccine may be higher than the rate of ICU admission from VITT in areas of moderate, high, or very high COVID-19 activity and in areas where the COVID-19 incidence rate is increasing, in some circumstances (considering other individual risk factors such as risk of exposure, summarized in the Risk Assessment Tool). NACI cautions that in age groups

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younger than 30 years of age, the benefit of offering a viral vector COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty, especially in areas of very low COVID-19 activity. On the other hand, the advantages of highly efficacious mRNA COVID-19 vaccines, with no safety signals of concern to date, clearly outweigh any possible disadvantages for most populations, and NACI made a strong recommendation for the preferential use of mRNA COVID-19 vaccines in all authorized age groups.

A summary of the evidence and rationale for NACI's strong preferential recommendation for the use of mRNA COVID-19 vaccines in population-level programs and discretionary recommendation for the use of a viral vector COVID-19 vaccine for individuals 30 years of age and older who do not wish to wait for an mRNA vaccine is below:

- **Epidemiology**: The epidemiology and risk of COVID-19 vary across Canada and between populations. The incidence of cases due to VOC in Canada is increasing, particularly among younger individuals, but differences in risk for severe outcomes due to VOC by age group have yet to be determined. NACI will continue to monitor the evolving epidemiology. The benefit of a viral vector COVID-19 vaccine increases in regions of moderate, high, or very high epidemic transmission of SARS-CoV-2 strains for which these vaccines offer protection and in areas of increasing COVID-19 incidence rates.
- **Efficacy and Effectiveness**: Emerging data suggests that all authorized vaccines offer protection against hospitalization and likely also death from COVID-19. In clinical trials, mRNA COVID-19 vaccines demonstrated higher efficacy than was shown for the viral vector COVID-19 vaccines. There is evidence that both the Pfizer and AstraZeneca COVID-19 vaccines offer protection against the B.1.1.7 SARS-CoV-2 variant. Pfizer and Janssen COVID-19 vaccines seem to offer protection against the B.1.351 SARS-CoV-2 VOC, but the AstraZeneca COVID-19 vaccine does not. In studies in Brazil, the Janssen vaccine was shown to offer protection against the P2 variant There is limited evidence on the protection of mRNA or viral vector COVID-19 vaccines against the P.1 variant.
- **Safety and VITT**: Evidence on the association between VITT following vaccination with the viral vector COVID-19 vaccines is evolving but the association has been confirmed. Several countries have paused the AstraZeneca COVID-19 vaccination program while others have restricted its use to certain age groups (from 30 years and over to 70 years and over). The Janssen vaccination program in the United States was paused to investigate cases of VITT; however, this pause was lifted on April 23 after a review of the data. No clear pattern or predisposing risk factors have been identified to date among cases of VITT. Though most cases in the United States to date have been identified in females younger than 50 years of age who received the Janssen vaccine, cases in males are being investigated and the case that has now been linked to this syndrome in the clinical trial was a male. Initial cases of VITT after vaccination with AstraZeneca COVID-19 vaccine were also seen in younger females; however, this is no longer the case as reports of VITT in older adults and in males have been confirmed.
- **Public health benefit-risk assessment:** Age-based benefit-risk analyses were conducted to determine if the benefit of earlier vaccination with a viral vector COVID-19 vaccine (instead of waiting for an mRNA vaccine) outweighs the risk of harms from VITT across various levels of COVID-19 activity (very low, low, moderate, high, very high). At the time the analyses were conducted, the risk of severe COVID-19 outcomes (such as ICU admissions and death) exceeded the risk of VITT in adults 30 to 69, in areas of moderate, high or very high epidemiology under most conditions. The benefits of earlier vaccination with AstraZeneca COVID-19 vaccine in younger age groups and in areas with low COVID-19 activity were more sensitive to change, depending on the assumed rate of VITT, which continues to change rapidly as new cases are identified. A benefit-risk

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assessment was not completed for adults 70 years or older for either viral vector vaccine as mRNA vaccine is already available to this age group in Canada. Refer to Appendix E for details on, and limitations of, this analysis.

- **Ethics**: NACI consulted with the Public Health Ethics Consultative Group (PHECG) on the ethical considerations for restricting the use of a viral vector vaccine in the current and anticipated pandemic and vaccine supply context. The PHECG provided recommendations in the following areas: promoting well-being and minimizing risk of harm, maintaining trust, respect for persons and fostering autonomy, and promoting justice and equity. NACI integrated these recommendations into its guidance (e.g., enabling respect for persons and autonomy by incorporating informed consent into the discretionary recommendation for use of a viral vector vaccine; promoting justice and equity by specifically identifying risks to exacerbating inequities in the Risk Assessment Tool). NACI applied the precautionary principle in making its discretionary recommendation, and took into account the evolving evidence on VITT, the potential for harm, biologic plausibility for a class effect with the viral vector vaccine platform common to the AstraZeneca and Janssen COVID-19 vaccines, the availability of other effective vaccines without this safety signal, as well as evidence of the effectiveness of alternate infection prevention and control measures.
- **Equity**: NACI examined the implications of various recommendation options on the opportunity for all populations to have a fair opportunity to attain their full health potential [(2)]. Populations that receive a viral vector COVID-19 vaccine may have protection against COVID-19 disease earlier than if they had waited for mRNA vaccines to be available. However, these populations may ultimately have lower protection, as a larger proportion of the vaccinated population will remain susceptible. NACI considered the impact of the provision of a less efficacious vaccine with a safety signal of concern to marginalized and disadvantaged populations who have been disproportionately affected by the pandemic, and whose lived experience may have led to distrust of governments. Depending on vaccination strategies, this could potentially exacerbate health inequities if this potential harm is not considered when implementing the vaccine program in populations who experience intersecting risk factors for severe disease and exposure (e.g., racialized populations living in multigenerational housing with over-representation in jobs providing essential services such as food and healthcare). The risk of COVID-19 to individuals and their families who have limited ability to reduce their personal risk of infection or who work in occupations with direct close physical contact with the public, the anticipated waiting time for an mRNA vaccine, and the individual's risk tolerance to wait for an mRNA vaccine should be considered. This may vary across Canada and between populations, so the Risk Assessment Tool may be used to assist with decision-making.
- **Feasibility**: NACI considered the impact of its recommendations on the successful implementation of COVID-19 immunization programs in the local setting with available resources [(2)]. Canada has procured and is expecting enough supply of mRNA vaccines to enable vaccination of currently eligible Canadian population before fall 2021, with enough supply to enable all eligible Canadians to receive their first dose by June 2021. Expected supplies of viral vector COVID-19 vaccines for Canada are minimal in comparison to expected supplies of mRNA vaccines in the coming weeks. Therefore, the anticipated waiting time to receive an mRNA vaccine will soon be reduced but may vary between populations and across jurisdictions. While the mRNA COVID-19 vaccines have more challenging storage and transportation requirements than the viral vector COVID-19 vaccines, infrastructure now exists to support the use of ultra-frozen and frozen mRNA vaccines. The Janssen vaccine is authorized as a single dose vaccine; however, the duration of protection against COVID-19 is unknown.

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- **Acceptability**: NACI reviewed recent Canadian data to consider the potential impact of its recommendations on intention and behaviours toward COVID-19 vaccination. The desire to be vaccinated continues to rise. However, various populations who have been disproportionately affected by the pandemic are also more hesitant or experience barriers in receiving a COVID-19 vaccine (e.g., racialized populations, migrant or undocumented workers). While public opinion research conducted in March suggested 44-60% of Canadians had no preference on which vaccine they received, surveys conducted in early April found that Canadians who are planning to get vaccinated are far more comfortable with the mRNA vaccines (90-92%) than the Janssen (70%) or AstraZeneca (41%) vaccines [28]. Data collected over the course of the pandemic have consistently found that Canadians cite "ensuring the safety of the vaccine" as the main reason for delaying or not getting COVID-19 vaccination. NACI transparently summarized the best available evidence (including knowns and unknowns) to develop its evidence-informed expert guidance and enhance trust and confidence in its recommendations.

3. **Based on emerging evidence of the protection provided by the first dose of a two-dose series for COVID-19 vaccines currently authorized and available in Canada, NACI recommends that in the context of limited COVID-19 vaccine supply and ongoing pandemic disease, jurisdictions should maximize the number of individuals benefiting from the first dose of vaccine by extending the second dose of COVID-19 vaccine *up to four months* after the first. Second doses should be offered as soon as possible after all eligible populations have been offered first doses, with priority given to those at highest risk of severe illness and death from COVID-19 disease. Vaccinated people (with one or two doses) should continue to follow recommended public health measures. NACI will continue to monitor the evidence on effectiveness of an extended dose interval and will adjust recommendations as needed. *(Strong NACI Recommendation)***

Jurisdictions may choose to shorten the time between the first and second dose of a two-dose series for COVID-19 vaccines in specific population groups based on their local epidemiology, vaccine supply and vaccine delivery mechanisms.

Summary of evidence and rationale:

- Morbidity and mortality from COVID-19 is ongoing and vaccine supply is limited. Extending the interval to the second dose allows vaccination of the largest number of people as quickly as possible, providing more people with direct protection and the possibility of indirect and community protection.
- An extended interval of up to four months allows as many eligible populations as possible to be offered vaccination with one dose before proceeding to offer second doses. However, as soon as all eligible groups have been offered their first dose of vaccine, second doses should be offered. The interval between first and second dose should not be extended any longer than needed to offer first doses of vaccine to all eligible individuals.
- This recommendation applies to all two-dose COVID-19 vaccines currently authorized for use and available in Canada.
- Current evidence suggests very good vaccine efficacy against symptomatic COVID-19 from one dose of COVID-19 vaccines, with good effectiveness shown in observational studies (generally between 60 and 80%, with some lower and higher estimates) against symptomatic disease and/or asymptomatic infection, as well as very good effectiveness against hospitalization (approximately 80%) and death (approximately 85% based on one

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study from the UK). While two doses of mRNA vaccines have shown excellent efficacy and effectiveness, one dose of mRNA vaccines appear to perform similarly to one or two doses of the AstraZeneca vaccine.

- Effectiveness has been documented for up to two months after the first dose of the mRNA vaccines, and the AstraZeneca clinical trial publication modelled one-dose efficacy up to 90 days after vaccination.
- Informed expert opinion based on principles of immunology indicate that a longer interval between priming and boosting doses of a vaccine series results in a better, more durable response. The AstraZeneca COVID-19 vaccine clinical trial demonstrated optimal efficacy when the interval between the first and second doses was ≥12 weeks.
- In situations where informed consent included assumptions about second dose timing, jurisdictions may consider offering second doses at shorter intervals for those who provided consent for the vaccine series prior to implementation of this recommendation.
- Because of ongoing disease transmission and less than complete individual protection from vaccination in either one-dose or two-dose vaccinated people, ongoing compliance with public health measures (masking, physical distancing and limiting social interactions as per public health guidance) should continue at this time.
- The vaccine effectiveness of the first dose will be monitored closely and the decisions regarding the second dose will be continuously assessed based on surveillance and effectiveness data and post-implementation study designs. In addition, effectiveness against variants of concern will also be monitored closely. If indicated based on these data, recommendations will be revised to offer earlier second doses to some cohorts or population groups.

Please see NACI's Statement on Extended dose intervals for COVID-19 vaccines to optimize early vaccine rollout and population protection in Canada in the context of limited vaccine supply for a summary of the evidence and further rationale for this recommendation.

4. **NACI recommends that all individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.** ***(Strong NACI Recommendation)***

Summary of evidence and rationale

- Currently, there is insufficient evidence on the duration of protection of COVID-19 vaccines and the effectiveness of COVID-19 vaccines in reducing transmission of SARS-CoV-2. Evidence of protection against asymptomatic SARS-CoV-2 infection is emerging for the mRNA and Janssen vaccines, but the evidence is insufficient at this time to recommend discontinuation of public health measures. NACI will continue to monitor the evidence and update recommendations as needed.
- Although effectiveness against symptomatic disease and/or asymptomatic infection appears to be very high for two doses of mRNA vaccines (~90-95%), some individuals will still remain susceptible even after two doses of vaccine. One dose of an mRNA vaccine and one or two doses of the AstraZeneca vaccine have good, but somewhat lower, effectiveness, and does not appear to protect against asymptomatic infection based on clinical trial results. Therefore adherence to public health measures in vaccinated individuals (one or two doses) remains very important at this time when SARS-CoV-2 continues to circulate widely.
- Evidence of protection offered by COVID-19 vaccines against VOC is evolving (see Table 5).

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- There is evidence to support the effectiveness of other recommended public health measures in pre-exposure and post-exposure scenarios, including physical distancing, masking, hand hygiene, as well as isolation and quarantine.
- Currently, there is no evidence on the use of COVID-19 vaccine for post-exposure prophylaxis.
- Federal, provincial/territorial, and local public health measures for the prevention and control of SARS-CoV-2 should continue to be followed.

5. **NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection.** ***(Discretionary NACI Recommendation)***

Summary of evidence and rationale:

- Testing for previous SARS-CoV-2 infection is not needed prior to COVID-19 vaccination.
- On March 30, NACI reaffirmed its recommendation that those previously infected with SARS-CoV-2 be offered a complete series with a COVID-19 vaccine, after considering evidence from observational studies that reported on the immunogenicity and safety of vaccination in previously infected individuals, safety data from pivotal clinical trials of vaccines approved for use in Canada, as well as presentations from the Canadian National Vaccine Safety Network and the University of Montreal RECOVER study.
- In the absence of one-dose vaccine effectiveness data in previously infected individuals (particularly as it relates to the variants of concern), limited second-dose safety data (i.e. impact of disease severity and the interval since previous infection on reactogenicity), and the potential programmatic challenges associated with the communication and implementation of a one-dose strategy, people with previous SARS-CoV-2 infection should continue to receive a complete vaccine series at the recommended intervals, regardless of the severity of their previous infection.
- Currently, there is a lack of evidence on potential differences in vaccine efficacy between those with and without prior evidence of SARS-CoV-2 infection. In COVID-19 vaccine clinical trials to date, individuals with PCR-confirmed SARS-CoV-2 were excluded and there were only a small number of trial participants with serologic evidence of previous infection (IgG+) who had confirmed symptomatic COVID-19 during the trials, therefore efficacy in this population is uncertain.
- There is currently limited data on potential differences in reactogencity between those with and without prior evidence of SARS-CoV-2 infection. There is a lack of evidence regarding the impact of the severity of the previous infection and the impact of the interval between a previous infection and timing of the first dose on reactogenicity.
- The immune response to SARS-CoV-2 and variants of concern, including duration of immunity and cross-protection, is not yet well understood. Reinfections with SARS-CoV-2 and variants have been reported and research to establish the severity, frequency, and risk factors of reinfection is ongoing. There is limited data suggesting individuals with previous infection may generate a comparable or greater immune response to a single dose of vaccine compared to SARS-CoV-2 naïve individuals after receiving 2 doses.
- In the context of limited supply, to allow for the protection of a larger number of at-risk individuals, vaccination with a COVID-19 vaccine may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first three months following infection. However, if challenging from a feasibility perspective,

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jurisdictions may elect to disregard prior PCR-confirmed SARS-CoV-2 infection status and vaccinate everyone in a given key population.

- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, and to minimize the risk of transmission of COVID-19 at an immunization venue, NACI recommends that symptoms of an acute illness are completely resolved before vaccinating with COVID-19 vaccine, as well as ensuring that the individual is no longer considered infectious based on current criteria.
- NACI will continue to monitor the evidence regarding vaccination in those previously infected with SARS-CoV-2 and will update recommendations as needed.

NACI also makes the following recommendations for COVID-19 immunization in some specific populations who were either excluded from or were represented by small numbers of participants in clinical trials. Vaccine may be offered to some individuals in these populations in some circumstances on a case-by-case basis with a risk-benefit analysis (where the risk of exposure and/or severe COVID-19 disease outweighs the risk of vaccination), and with transparency about the limited evidence. Preference for mRNA COVID-19 vaccine (as outlined in Recommendation #1, above), if available, also applies to the populations described below.

NACI will be reassessing these recommendations as more evidence has become available.

Immunosuppressed persons

6. **NACI recommends that a complete COVID-19 vaccine series may be offered to individuals who are immunosuppressed due to disease or treatment in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the limited evidence on the use of COVID-19 vaccines in this population and the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines. (*Discretionary NACI Recommendation*)**

Summary of evidence and rationale

- Currently, there is limited evidence that immunosuppression is an independent risk factor for severe COVID-19, though evidence is evolving. A rapid review of evidence from OECD member countries found a low certainty of evidence for no association with mortality or hospitalization due to COVID-19 in those with unspecified immunosuppression [4]. The review found a low certainty of evidence for at least a two-fold increase in mortality due to COVID-19 for those with sickle cell disease or severe immunodeficiency; metastatic cancer; chemotherapy in the past 12 months or radiotherapy in the past 6 months; solid organ, bone marrow, or stem cell transplant. Caution should be taken when interpreting low certainty evidence. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found.
- Currently, there are limited data on COVID-19 vaccination in individuals who are immunosuppressed. Participants in the COVID-19 vaccine clinical trials only included individuals who were not immunosuppressed, such as those with stable infection with

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human immunodeficiency virus (HIV), and those not receiving immunosuppressive therapy during the trial.

- No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition (e.g., stable HIV infection) included in the clinical trials.
- The relative degree of immunodeficiency in individuals who are immunocompromised is variable depending on the underlying condition, the progression of disease and use of medications that suppress immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- In general, non-replicating vaccines may be administered to immunocompromised people because the antigens in the vaccine cannot replicate. However, the magnitude and duration of vaccine-induced immunity are often reduced. It is currently unknown whether immunocompromised individuals will be able to mount an immune response to the authorized COVID-19 vaccines.
- People living with HIV who are considered immunocompetent may be vaccinated.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization of Immunocompromised Persons in the CIG, Part 3 – Vaccination of Specific Populations for definitions and additional general information.

Persons with an autoimmune condition

7. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals with an autoimmune condition in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the limited evidence on the use of COVID-19 vaccines in these populations. (*Discretionary NACI Recommendation*)**

Summary of evidence and rationale

- The evidence that having an autoimmune condition is an independent risk factor for severe COVID-19, is evolving. A rapid review of evidence from OECD member countries found strong evidence (of moderate or high certainty) for at least a 2-fold increase in mortality from COVID-19 with type 1 diabetes, as well as with a group of neurological disorders including multiple sclerosis and myasthenia gravis. The review found a low certainty of evidence of little or no association with mortality and a moderate certainty of evidence for little or no association with hospitalization from COVID-19 in those with rheumatoid arthritis, rheumatic disease, or systemic lupus erythematosus. Caution should be taken when interpreting low certainty evidence [4]. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found.
- Currently, there are very limited data on COVID-19 vaccination in individuals who have an autoimmune condition. Although participants with autoimmune conditions who were not immunosuppressed were not excluded from trials, they constitute a very small proportion of trial participants and represent a very narrow range of autoimmune conditions.

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- The spectrum of autoimmune conditions is diverse. The relative degree of autoimmunity in individuals with autoimmune conditions is variable depending on the underlying condition, the severity and progression of disease, and use of medications that impact immune function. Therefore, the balance of benefits and risks must be made on a case-by-case basis.
- Other applications of mRNA technologies have been for the treatment of cancer, which requires an immune response directed against an individual's cancer cells. This raised the theoretical concern that mRNA vaccines for infectious diseases would behave similarly, eliciting inflammation and possibly exacerbating existing autoimmune diseases. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk; however, further evaluation is needed.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Persons with Chronic Diseases in the CIG, Part 3 – Vaccination of Specific Populations for additional general information on autoimmune conditions.

Pregnancy and Breastfeeding

8. **NACI recommends that a complete vaccine series with a COVID-19 vaccine (preferably with an mRNA COVID-19 vaccine)** may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the evidence on the use of COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)**

   **An mRNA vaccine is preferred due to published safety data and concerns about treatment of VITT in pregnancy, should it occur. Recently published preliminary analyses of 35,691 pregnant women in the United States who received an mRNA COVID-19 vaccine did not reveal any obvious safety signals [29]. If VITT were to occur after receipt of a viral vector vaccine in a pregnant person, there is increased complexity in the medical care.

9. **NACI recommends that a complete vaccine series with a COVID-19 vaccine may be offered to individuals in the authorized age group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the limited evidence on the use of COVID-19 vaccines in this population. (*Discretionary NACI Recommendation*)**

Summary of evidence and rationale

- The evidence of pregnancy as an independent risk factor for severe COVID-19 is evolving. A rapid review of evidence from OECD member countries found a low certainty of evidence of at least a two-fold increase in hospitalization due to COVID-19 for pregnancy (any stage). Caution should be taken when interpreting low certainty evidence [4]. However, the review found a moderate certainty of evidence of at least a two-fold increase in hospitalization and mortality if an individual had two or more underlying medical conditions, compared to individuals with no comorbidities. No direct evidence on the combination of medical conditions associated with increased risk was found
- Pregnant or breastfeeding individuals were excluded from the mRNA and viral vector COVID-19 clinical trials. Outcomes in participants who became pregnant during the clinical trials and fetal outcomes will be reported through registries.

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- NACI encourages research on COVID-19 vaccination in pregnancy and during breastfeeding.
- Emerging research suggests that COVID-19 mRNA vaccination during pregnancy results in comparable antibody titres to those generated in non-pregnant women. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream.
- Early studies consistently show that both anti-spike IgG and IgA are present in breastmilk after maternal vaccination with mRNA vaccines.
- In one small cohort study, mRNA from COVID-19 vaccines was undetectable in breastmilk 4-48 hours post-vaccination.
- Currently, there are limited data on the safety of COVID-19 vaccine from animal developmental and reproductive toxicity studies. In rats that received the Moderna COVID-19 vaccine prior to or during gestation, no safety concerns regarding female reproduction, fetal/embryonal development, or postnatal development were demonstrated. According to a report presented to the European Medicines Agency (EMA), studies in rats using four full doses of the Pfizer-BioNTech COVID-19 vaccine did not indicate adverse effects with respect to fertility, pregnancy, embryo/fetal development, or postnatal development, up to day 21. A US Food and Drug Administration (FDA) review of a study in rabbits that received the Janssen COVID-19 vaccine at two times the human dose prior to or during gestation concluded there were no adverse effects on female reproduction, fetal/embryonal development, or postnatal development. Developmental and Reproductive Toxicity (DART) animal studies for the AstraZeneca COVID-19 vaccine are ongoing.
- Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received a COVID-19 vaccine.
- If pregnancy is determined after initiation of the vaccination series, completion of the series may be delayed until after pregnancy, unless risk factors for increased exposure or severe COVID-19 are present and informed consent for vaccination is obtained as above.
- Eligible individuals should be offered a complete vaccine series with an authorized COVID-19 vaccine post-partum and prior to attempting pregnancy so that the recommended interval between completion of the vaccine series and conception is maintained.
- Vaccine recipients and health care providers are encouraged to enroll patients who have received a COVID-19 vaccine during pregnancy in COVID-19 vaccine pregnancy registries (refer to Appendix G for a list of COVID-19 vaccine pregnancy registries). Timely reporting on adverse events following immunization to the local public health authority, as well as to the vaccine manufacturer, for follow up in these vaccine recipients is strongly encouraged.
- NACI will monitor the evidence as it evolves, and update recommendations as needed.

Refer to Immunization in Pregnancy and Breastfeeding, Part 3 – Vaccination of Specific Populations of the CIG for additional general information.

Children and Adolescents

10. NACI recommends that COVID-19 vaccines should not be offered routinely to individuals who are not in the authorized age group. *(Strong NACI Recommendation)*.

a. However, a complete vaccine series with a Pfizer-BioNTech may be offered to individuals 12-15 years of age who are at very high risk of severe outcomes of

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COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) or are at increased risk of exposure (e.g., due to living in a congregate care facility), if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent with the individual and the parent or guardian includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in this population. ***(Discretionary NACI Recommendation)***

Summary of evidence and rationale

- Evidence to date suggests that in general, children infected with SARS-CoV-2 are not at increased risk of severe disease. A rapid review of evidence from OECD member countries found a low certainty of evidence of at least a two-fold increase in hospitalizations due to COVID-19 among children (≤18 years of age) with obesity, hypertension, or immunodeficiency, compared to children without these conditions. Caution should be taken when interpreting low certainty evidence.
- Evidence on COVID-19 vaccination in those less than 12 years of age is absent, and only limited clinical data on the use of the Pfizer-BioNTech COVID-19 vaccine in those aged 12 to 15 years is available. The Moderna COVID-19 vaccine and AstraZeneca COVID-19 vaccine clinical trial results have to date only included adults 18 years of age and older. Clinical trials in children less than 18 years of age have been initiated and are ongoing; NACI is monitoring the evidence and will update recommendations when results become available.
- For adolescents with certain pre-existing medical conditions compounded by an increased risk of exposure to SARS-CoV-2 (e.g., due to living in a congregate setting such as a group home), the balance of risks and benefits of vaccination with a COVID-19 vaccine must be made on a case-by-case basis.
- Active surveillance in these vaccine recipients is strongly encouraged. NACI will monitor the evidence as it evolves, and update recommendations as needed.

NACI continues to recommend the following:

- Routine immunization programs and immunization with other vaccines recommended by NACI should continue during the COVID-19 pandemic with mitigation of risks of COVID-19 transmission during the immunization process as outlined in the Interim guidance on continuity of immunization programs during the COVID-19 pandemic.

- Clinical trials assessing COVID-19 vaccines should continue to be encouraged to include individuals with potential vulnerabilities to disease related to biological (e.g., pre-existing medical conditions, frailty, pregnancy and breastfeeding, immunocompromised), and social (e.g., residence in long term care facilities or crowded/remote locations, belonging to a racialized population, occupation) factors to ensure that vaccine options are informed by robust safety, immunogenicity, and efficacy data as outlined in NACI's guidance on Research Priorities for COVID-19 Vaccines to Support Public Health Decisions

- In addition to ongoing vaccine pharmacovigilance activities in Canada with Phase 4 clinical trials and post-marketing studies, additional research and surveillance of COVID-19 vaccination, particularly in populations not currently included in clinical trials (e.g., pregnant, breastfeeding, immunosuppressed, seniors living in congregate care settings, children and adolescents) is recommended. Furthermore, NACI recommends the continuation of clinical trials and ongoing follow-up of participants for as long as it is

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ethically feasible to determine the level of immunity needed to prevent disease, duration of protection, efficacy in different sub-populations, and medium- and long-term safety.

Refer to Vaccine Safety and Pharmacovigilance in the CIG, Part 2 – Vaccine Safety for additional information.

NACI continues to recommend the following elements to guide ethical decision-making, as outlined in NACI's guidance on Key Populations for Early COVID-19 Immunization**:**

- Efforts should be made to increase access to immunization services to reduce health inequities without further stigmatization or discrimination, and to engage systemically marginalized populations and racialized populations in immunization program planning.

- Jurisdictions should ensure close and rapid monitoring of safety, effectiveness, and coverage of the vaccines in different key populations, as well as effective and efficient immunization of populations in hardly reached, remote and isolated communities.

- Efforts should be made to improve knowledge about the benefits of vaccines in general and of COVID-19 vaccines as each becomes available, address misinformation, and communicate transparently about COVID-19 vaccine allocation decisions.

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V.I MANAGEMENT OPTIONS FOR COVID-19 VACCINES AUTHORIZED FOR USE IN CANADA

There are currently four authorized COVID-19 vaccines in Canada for the prevention of symptomatic COVID-19 that use two different vaccine platforms. To assist with the decision on which vaccine to offer to different populations or groups, a comparison of the relative merits of both have been summarized in Table 5 below. Caution should be taken when comparing vaccines due to differences in studies conducted for each vaccine (e.g., different endpoints, different analyses, different time periods/countries and circulating strains).

Table 5. Management options for types of COVID-19 vaccines authorized for use in Canada

Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
Efficacy and Effectiveness	**Efficacy against symptomatic illness after a complete series** • Pfizer-BioNTech vaccine is overall 94% efficacious ≥14 days after dose 2 in study participants 18 years of age and older. Data suggests the Pfizer/BioNTech vaccine is 95% efficacious in participants ≥65 years of age 7 or more days after dose 2. • Moderna vaccine is overall 94% efficacious in participants 18 years of age and older ≥14 days after dose 2. • Data suggests the Moderna vaccine is 86% efficacious in individuals ≥65 years of age ≥14 days after dose 2. **Effectiveness against severe disease, hospitalization and death** • Current data from real-world studies suggests that mRNA COVID-19 vaccines provide good protection against COVID-19 hospitalization >14 days after the first dose, including in older populations (≥65 years). • Data from real-world studies provide some evidence that the first dose of mRNA COVID-19 vaccines provide very good protection against COVID-19-related death. • Limited data from real-world studies suggests the Pfizer-BioNTech COVID-19 vaccine has high vaccine effectiveness >7 days after the second dose against severe disease and COVID-19 related hospitalization and death. • Effectiveness data on the Moderna COVID-19 vaccine alone is not currently available.	**Efficacy against symptomatic illness after a complete series** • AstraZeneca SD/SD vaccine is 62% efficacious in participants 18 to 64 years of age. • Current data from clinical trials are insufficient to determine the efficacy of the AstraZeneca vaccine in individuals ≥65 years of age. • The interval between the first and second dose of the AstraZeneca vaccine may impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. • The Janssen COVID-19 vaccine (1 dose) is 66.9% and 66.1% efficacious against confirmed symptomatic moderate to severe/critical COVID-19 infection at ≥14 days and ≥28 days post-vaccination, respectively. • The Janssen COVID-19 vaccine is 76.7% and 85.4% efficacious against confirmed symptomatic severe/critical COVID-19 infection at ≥14 days and ≥28 days post-vaccination, respectively. **Effectiveness against symptomatic illness and hospitalization** • Observational data in individuals ≧65 years of age have shown a reduction in the risk of symptomatic disease and hospitalization with one dose of AstraZeneca vaccine. • Effectiveness data on the Janssen COVID-19 vaccine is not currently available.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	Efficacy against asymptomatic infection • A preliminary analysis of limited data in an ongoing trial suggests the Moderna COVID-19 vaccine may be efficacious in preventing asymptomatic infection, however data is still being collected and the final analysis is not complete. **Effectiveness against asymptomatic infection** • Estimates of vaccine effectiveness for the Pfizer-BioNTech COVID-19 vaccine against SARS-CoV-2 infection with no reported symptoms was moderate to high after the first dose (depending on time since vaccination) and high after the second dose [9, 15]. Similar results were reported for mRNA COVID-19 vaccines in general [16].	**Efficacy against asymptomatic infection** • An exploratory ad hoc analysis of limited data suggests the AstraZeneca vaccine may not be efficacious in preventing asymptomatic infection. • Preliminary analyses of limited data suggests that the Janssen COVID-19 vaccine has an estimated efficacy of 59.7% against asymptomatic or undetected SARS-CoV-2 infection with onset ≥28 days post-vaccination.
	Re-vaccination • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern. • Re-vaccinating those who initially received an mRNA vaccine with the same or another mRNA vaccine is currently being investigated. • The efficacy and safety of re-vaccinating those who initially received mRNA vaccine with a different COVID-19 vaccine are unknown at this time but are being investigated.	**Re-vaccination** • It is not yet clear if booster doses (e.g., annual vaccination) will be required to provide long-term protection against symptomatic COVID-19 disease, in particular with the emergence of variants of concern • Re-vaccination with a booster dose of viral vector vaccines may reduce vaccine effectiveness due to the possible development of immunity to the viral vector which may interfere with the immune response to subsequent doses. However, this is still being investigated. • The efficacy and safety of re-vaccinating those who initially received a viral vector vaccine with a different COVID-19 vaccine are unknown at this time.
Immunogenicity	**Humoral response** • Humoral responses for both mRNA COVID-19 vaccines in clinical trials peaked after a second dose, including elicitation of neutralizing antibodies. However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with protection.	**Humoral response** • For the AstraZeneca vaccine, humoral responses in clinical trials peaked after a second dose, including elicitation of neutralizing antibodies, for seronegative vaccine recipients. For seropositive vaccine recipients, humoral responses peaked at the first dose and maintained or decreased at the second dose.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	• Humoral responses in clinical trials had similar trends in individuals 18 to 55 years of age and individuals 65 to 85 years of age. • In observational studies, humoral responses in seropositive vaccine recipients after the first dose were comparable to those observed in SARS-COV-2 naïve individuals following administration of the second dose. However, as a correlate of protection is not known, the significance of these findings as they relate to the level of protection against reinfection is unknown [17][18][19, 20][21][22].	• For the AstraZeneca vaccine, humoral responses in clinical trials were lower in individuals ≥65 years of age and older, compared to individuals 18 to 64 years of age in unpublished data presented to NACI. Conflicting results have been shown for other age groups in recently published data [30]. • For the Janssen vaccine, humoral responses in clinical trials, including binding antibodies, neutralizing antibodies and antibodies with Fc effector functions, were seen by day 29 after one dose. • For the Janssen vaccine, somewhat lower humoral immune responses were seen in older age cohorts (>65) compared to younger cohorts (18 to 55) in clinical trials. • However, as a correlate of protection is not known, these humoral responses cannot be interpreted as corresponding with vaccine protection.
	Cellular response • Both mRNA vaccines have been shown to produce a cellular immune response by one to two weeks after administration of a second dose. • Increases in cellular immune responses response were seen in both younger and older adults. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.	**Cellular response** • The AstraZeneca vaccine has been shown to produce cellular immune responses that did not appear to increase after the second dose. • Cellular immune responses do not appear to differ between age groups. • For the Janssen vaccine, cellular immune responses were elicited after one dose of vaccine. • As no immunological correlate of protection has been determined for SARS-CoV-2, these cellular responses cannot be interpreted as corresponding with vaccine protection.
Protection against variants, including variants of concern	**B.1.1.7 (identified in UK)** • In countries where B.1.1.7 was the dominant circulating strain (>90% of sequenced samples), estimates of vaccine effectiveness of the Pfizer-BioNTech vaccine were comparable to vaccine efficacy against the parent strain.	**B.1.1.7 (identified in UK)** • Data suggest AstraZeneca vaccine has a vaccine efficacy against B.1.1.7 that is comparable to that against non-B.1.1.7 disease (74.6% vs. 84.1% respectively) [31]. **B.1.351 (identified in South Africa)**

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
	B.1.351 (identified in South Africa) • There are emerging data on the efficacy or effectiveness of mRNA vaccines against B.1.351. **P.1 and P.2 (identified in Brazil)** • There are limited data on the efficacy or effectiveness of mRNA vaccines against P.1 (variant of concern) and P.2 (variant of interest).	• Data suggest AstraZeneca vaccine has a vaccine efficacy of 10.4% against B.1.351 against mild to moderate illness [32]. • In South Africa, where B.1.351 was the dominant strain (approximately 95% of preliminary sequenced samples), the Janssen vaccine was 64% efficacious against moderate to severe/critical COVID-19 as of Day 29. **P.1 and P.2 (identified in Brazil)** • There are limited data on the efficacy or effectiveness of viral vector vaccines against P.1. • In Brazil, where P.2 was detected in approximately 70% of sequenced samples of COVID-19 cases, the Janssen vaccine was 68% efficacious against moderate to severe/critical COVID-19 as of Day 29.
Safety	**Technology** • mRNA vaccines use a new technology (which has been studied in experimental vaccines); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.	**Technology** • Viral vector vaccines use a relatively new technology (the authorized Ebola vaccine uses this technology); however, all COVID-19 vaccines undergo the same rigorous review and approval process as routine vaccines.
	Safety Signals • There have been no serious safety signals identified with either mRNA vaccine. Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines. • For both vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine recipients; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events, including fever, are more frequent after the second dose.	**Safety Signals** • For both vaccines, some solicited adverse events are reported to be very common (defined as 10% or more) among vaccine; however, they are mild or moderate and transient, resolving within a few days. These include: pain at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. Some adverse events are less frequent after the second dose. • For the AstraZeneca vaccine, rare cases of thrombosis and thrombocytopenia have been reported during post-licensure use. The mechanism of action appears to be similar to spontaneous heparin-induced thrombocytopenia (called VITT-Vaccine-Induced Immune Thrombotic Thrombocytopenia). The rate of this adverse event is still to be confirmed but is most commonly estimated to

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
		be between 1/100,000 and 1/250,000 people vaccinated with AstraZeneca vaccine. Case fatality of VITT depends on prompt detection, diagnoses and treatment and typically ranges between 25 and 40%. • For the Janssen vaccine, in the clinical trial, one case of cerebral venous thrombosis was reported among 21,895 vaccine recipients. As of April 28, 17 cases of VITT have been confirmed out of 8 million doses of Janssen vaccine administered in the United States. Investigations are ongoing.
Ethics and Equity	• mRNA vaccines have high short-term efficacy in all authorized age groups and Canada anticipates having enough doses of mRNA vaccines for every individual in Canada in 2021. • Vaccines that are more efficacious may be directed to those who are most at risk of severe disease and exposure to limit the exacerbation of existing inequities. • The impact of not offering a less efficacious vaccine earlier to populations who would otherwise have to wait to receive an mRNA vaccine in areas with a high risk of transmission and infection, should take into consideration trust, justice, and the risk of doing harm vs good.	• Offering any COVID-19 vaccine to those who would otherwise have to wait to receive one could enhance equity. • If protection against COVID-19 disease cannot be boosted for those that received a lower efficacy vaccine first, significant inequities could be created for those who receive a viral vector vaccine compared to an mRNA vaccine, depending on which population groups received the viral vector vaccine. • The viral vector vaccines may offer an option for individuals who are allergic to mRNA vaccine ingredients or their containers. The impact of offering a less efficacious vaccine earlier to some populations should take into consideration trust, justice and the risk of doing harm vs. good.
Feasibility	**Vaccine schedule** • Both mRNA vaccines are given as a two-dose series. • The mRNA vaccines have an authorized schedule of 21 (for the Pfizer vaccine) or 28 days (for the Moderna vaccine) between dose one and dose two. NACI has recommended an extended interval between the first and second dose of up to 4 months to maximize the number of individuals who can be vaccinated as quickly as possible with available vaccine supplies. This could allow for more individuals to receive one dose of the vaccine and have some protection against symptomatic COVID-19 disease.	**Vaccine schedule** • The AstraZeneca vaccine is given as a two-dose series. The interval between the first and second dose of the AstraZeneca vaccine seems to impact efficacy of the vaccine, with lower efficacy if the interval is less than 12 weeks. NACI has recommended an extended interval between the first and second dose of up to 4 months to maximize the number of individuals who can be vaccinated as quickly as possible with available vaccine supplies. • The Janssen vaccine is authorized as a single dose. This may increase the feasibility of the completion of a vaccine series.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**
		• Vaccine recipients need to be advised of the VITT safety signal and the symptoms to watch for after vaccination.
	Storage requirements • The mRNA vaccines have more challenging transport and storage requirements, requiring frozen or ultra-frozen cold chains. Significant efforts have been undertaken to address these logistical complexities. The storage requirements for these vaccines increase the logistical complexity of offering these vaccines in some venues to increase access for various populations.	**Storage requirements** • The viral vector vaccines are easier to transport, store and handle than mRNA vaccines, and as a result, could be easier to use for wider distribution via pharmacies and primary healthcare providers. • The viral vector vaccines require storage and transport at +2 to +8°C, which uses standard cold chain infrastructure widely available in provinces and territories. • The storage requirements for these vaccines could increase access to the vaccine for various populations.
Acceptability	• It is possible that individuals will favor mRNA vaccines since they have higher proven efficacy. • Fewer cases of COVID-19 are expected after vaccination with a vaccine with high efficacy. The relatively low incidence of cases post-vaccination could positively affect acceptability of COVID-19 vaccines and vaccines in general.	• It is possible that individuals will favor the viral vector vaccines if it offers an earlier opportunity to receive a COVID-19 vaccine and is more convenient to access if they are available at more convenient locations due to ease of transport, storage and handling. • A greater number of COVID-19 cases are expected after vaccination with a vaccine that has lower efficacy. The relatively higher incidence of cases post-vaccination could negatively affect the public's acceptability of COVID-19 vaccines and vaccines in general. • The Janssen vaccine is given as a single dose. This may increase acceptability of vaccination. • Recent cases of VITT detected after administration with the viral vector vaccines have impacted their acceptability.

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Factor for consideration	Summary of available evidence and issues for consideration	
	mRNA COVID-19 Vaccines	**Non-replicating viral vector COVID-19 Vaccines**

	Concerns about vaccine safety and effectiveness are the two most cited reasons for vaccine refusal [33]
	• In a survey of Canadians conducted between February 9 and 16, 2021 [34], the following results were reported:
	  ○ Of those who indicated they have not yet been vaccinated (n=1954), more respondents 'Agreed' or 'Strongly Agreed' with items stating intention to get a 'safe vaccine' (69%) and an 'effective vaccine' (67%) since Wave 4 (late May-early June).
	  ○ When respondents who were willing or neutral towards getting vaccinated were asked what is most important with respect to selecting a COVID-19 vaccine to receive (n=1595), 46% selected "Receiving the most effective vaccine", 15% selected "Receiving any vaccine as soon as possible" and 12% selected "Receiving the vaccine with the fewest reported side effects". The number of doses and type of vaccine technology were not important factors, and 14% of respondents indicated they have no preference on what COVID-19 vaccine they receive.
	  ○ For those who will wait to get the vaccine once it is available: 80% will wait to ensure the safety of the vaccine, 64% will wait to ensure the effectiveness of the vaccine (n=691) [35]
	• In a survey of health care providers conducted on Dec 4-13, 2020 [36], the most important factors reported to influence the decision to receive vaccine were vaccine safety (95.5%), followed by vaccine effectiveness (86.7%) (n=14,336)	

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VI. RESEARCH PRIORITIES

COVID-19 disease and associated vaccines are novel; therefore, research is warranted in many areas. Research to address the following outstanding questions (not ordered in terms of importance) is encouraged, drawing from both short-term and long-term data, where available:

New and Emerging Research Priorities

Efficacy, Effectiveness, Immunogenicity and Safety

1. What is the population effectiveness (against infection/transmission, hospitalization and death) and medium and long-term duration of protection of a single dose or a complete series of each COVID-19 vaccine approved in Canada?

2. What is the efficacy, effectiveness, immunogenicity, and safety of COVID-19 vaccines across diverse population groups (e.g., adults of advanced age, those with high-risk medical conditions including autoimmune conditions and transplant recipients, individuals with social or occupational vulnerabilities, individuals who are pregnant or breastfeeding, children/adolescents, frailty)?

3. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines in individuals who have had a previous laboratory evidence of SARS-CoV-2 infection?
    a. Is there a discernable difference between seronegative and seropositive people in any of the above parameters?
    b. Does previous exposure to SARS-COV-2 impact efficacy, effectiveness, immunogenicity or safety of COVID-19 vaccines?
    c. Can a single-dose vaccine series be as effective and safe in individuals with previously proven COVID-19 disease?
    d. Are there any emerging safety signals with COVID-19 immunization that are not predicted by the current understanding of the safety profile of similar vaccines?
    e. Does vaccination following prior SARS-CoV-2 infection or vaccination of SARS-CoV-2 naïve individuals elicit enhanced or altered disease upon subsequent infection by SARS-CoV-2 or other endemic coronaviruses?

4. What is the efficacy, effectiveness, immunogenicity and safety of COVID-19 vaccines (including potential boosters) against SARS-CoV-2 VOC?

5. What is the correlate of protection for SARS-CoV-2? How are immune responses induced by natural infection similar or different from those induced by vaccines against COVID-19? Is SARS-CoV-2 natural infection (symptomatic or asymptomatic) associated with protection against re-infection or severe disease?

6. Further immunological evidence is needed in the following areas to inform efficacy predictions:
    a. How do immune responses change over time; what is the durability of immune responses against SARS-COV-2 over the long-term? What is the impact of vaccine dose or interval on durability?

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   b. Which immune responses are most important for protection from infection (adaptive or innate immunity), severe disease or transmissibility? What is the role of humoral vs. cellular immunity in preventing immune escape of viral variants?
   c. Are immunoglobulin (Ig)A/IgG/IgM antibodies protective against SARS-CoV-2 and what is the correlate of protection?

7. What level of COVID-19 vaccination coverage is required to achieve various public health milestones, including: coverage to reduce the burden on the health care system to a manageable degree, achieve herd immunity to protect non-vaccinated individuals, and remove PHM controls. What vaccine characteristics play the largest role on these milestones (i.e., efficacy, durability, uptake)?
8. What is the background level of Canadian vaccine-vector-specific responses (i.e., anti-Chimpanzee adenovirus)? Are these responses higher in some groups? Will these responses interfere with vaccine efficacy of these highly seropositive groups? What is the duration of anti-vector interference immunity following viral vector vaccines?
9. How will viral variants impact the efficacy, effectiveness, immunogenicity and safety of a vaccine with respect to death, severe disease, symptomatic disease, asymptomatic disease, infectivity and transmission? What is the effect of using booster vaccines containing heterologous antigens and what is the optimal timing for booster vaccination?
10. Are any components of the COVID-19 vaccine at high risk of inducing an anaphylactic reaction?
11. What is the incidence of rare, serious adverse events following immunization with COVID-19 vaccines?
    a. What is the incidence of thrombosis and thrombocytopenia including CVST and DIC after COVID-19 immunization and after infection with SARS-CoV-2? What is the trigger for the development of this adverse event following immunization and what can be done to mitigate its development?
    b. What is the exact biological mechanism by which viral vector vaccines may trigger VITT? Are VITTs a class effect of the adenovirus vector vaccines or are there separate mechanisms that are product-specific (e.g., due to differing dose and magnitude of immune response based on the nature of the vaccines)?
    c. How do age, sex, or other patient characteristics (e.g., pregnancy, health-seeking behaviours) affect the incidence of VITT and the complications of VITT?
12. Does endemic coronavirus infection history impact the course of SARS-CoV-2 disease? Is there cross-protection or interference from antibodies/exposure to human seasonal coronaviruses when exposed to SARS-CoV-2 or vaccinated against SARS-CoV-2?
13. Are there any negative interactions between COVID-19 vaccination and other medications? What is the recommended timing between COVID-19 vaccines and anti-SARS-CoV-2 prophylactic or therapeutic antibodies or convalescent plasma?
14. Does vaccination have an impact on the transmissibility of SARS-CoV-2 in individuals with asymptomatic infection?
15. What is the role of seasonal attenuation of SARS-CoV-2?

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16. How does vaccination impact individual-level variation in transmission (e.g., superspreaders)?
17. What is the epidemiology of SARS-CoV-2 VOC over time and across the country and its regions? What are the transmissibility and virulence (including hospitalizations and deaths) of the VOC?
18. What are the epidemiological characteristics of breakthrough illness (e.g., vaccine recipient characteristics, SARS-CoV-2 VOC)?

Vaccine Administration

19. Are any COVID-19 vaccines interchangeable to complete a regular vaccine series? What is the efficacy, effectiveness, immunogenicity and safety of a mixed dose schedule or a mixed dose booster series?
20. What are the minimum, maximum and optimal intervals between doses of a two-dose COVID-19 vaccine schedule that continue to provide protection against disease?
21. Are any other vaccines (e.g., Bacillus Calmette-Guérin) protective against COVID-19 through off-target effects?
22. Can COVID-19 vaccine be simultaneously administered with other, non-COVID-19 vaccines (either live or inactivated vaccines)? If not, what is the minimum interval between administrations?
23. Can COVID-19 vaccines be given in individuals who have received convalescent plasma or anti-SARS-CoV-2 spike protein monoclonal antibodies? If so, what is the minimum interval required for vaccine administration following receipt of convalescent plasma or monoclonal antibodies?

Standing Research Priorities

COVID-19 infection and disease

1. What is the epidemiological profile of COVID-19 (e.g., communicable period, all risk groups)?
    a. What is the disease distribution and spectrum of clinical illness for COVID-19, including burden of illness and risk by age, sex and other demographic variables associated with higher risk?
    b. What are the transmission dynamics of COVID-19, including degree of asymptomatic transmission, role of children in transmission, vertical transmissibility, onset and duration of viral shedding and communicable period, impact of changing weather conditions, and trends over time?
    c. What are the rates of COVID-19 co-infections with other respiratory pathogens and what is the impact on pathogenesis and clinical outcomes?
2. Can COVID-19 vaccine be used to protect household contacts of a case from infection? Does COVID-19 vaccination decrease infectiousness and clinical illness in individuals that have already acquired infection? Is COVID-19 vaccination effective in interrupting transmission?

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Ethics, Equity, Feasibility and Acceptability

3. What is the acceptability of (a) publicly funded COVID-19 vaccines and (b) other vaccines over time and over different epidemiological contexts among key populations, marginalized populations, providers and policy-makers in different epidemiological contexts across the country?
    a. What factors affect acceptability of immunization with a COVID-19 vaccine in these groups?
    b. What factors affect acceptability of immunization in general?
    c. How will acceptability of prioritized key populations for early immunization with COVID-19 vaccines evolve in different epidemiological contexts across the country?
    d. What strategies can improve acceptability of a COVID-19 vaccine in these groups?

4. How can vaccine allocation decisions be communicated to individuals and communities in order to maintain trust in public health authorities?

5. What COVID-19 vaccination strategies or implementation strategies can reduce health inequities in populations for whom the vaccination program is directly intended, and in populations for whom the vaccination program is not intended, but who are still impacted by it (e.g., impacted by the disease, spillover effects such as for caregivers, or externalities such as with herd immunity)?

6. Can a different COVID-19 vaccine be used to complete a primary series or as a booster dose? How are returning travellers managed if they have initiated but not completed a COVID-19 vaccine series abroad?

Health-Related Quality of Life and Well-being

7. What is the health-related quality of life or well-being of COVID-19 patients and caregivers over time (e.g., health utilities, patient-reported outcomes, patient-reported experiences measures)?

8. What is the impact of COVID-19 vaccination on health-related quality of life or well-being on individuals?

VII. SURVEILLANCE ISSUES

Ongoing and systematic data collection, analysis, interpretation and timely dissemination is fundamental to planning, implementation, evaluation, and evidence-informed decision-making. To support such efforts, NACI encourages surveillance improvements in the following areas:

1. Epidemiology

- Enhance social and socioeconomic data collected and made available to understand and address health inequities related to COVID-19
- Systematic examination of the Canadian burden and epidemiology of COVID-19 outbreaks by setting and severity, identifying high-risk activities, settings and populations

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- Evaluation of the success of public health interventions to minimize or prevent COVID-19 outbreak events, especially in vulnerable or high-risk communities

2. Laboratory (e.g., strain characterization)

- Enhance laboratory surveillance in order to provide early warning of increasing or decreasing activity by age, sex, and presence of symptoms, and help interpret case data based on changes to testing algorithms
- Conduct genomic surveillance to identify international and inter-provincial transmission and new strains/variants with differing severity, transmissibility, or vaccine comparability
- Explore other SARS-CoV-2 detection kits at point of care with immediate results.

3. Vaccine (coverage, effectiveness, safety)

- Reliably monitor coverage rates for each authorized COVID-19 vaccine in different key populations, ensuring data on series completion
- Ensure existing mechanisms for the evaluation of adverse events are positioned to generate data for each authorized COVID-19 vaccine

TABLES

Table 6. Strength of NACI Recommendations

Strength of NACI Recommendation *based on factors not isolated to strength of evidence* (e.g., public health need)	**STRONG**	**DISCRETIONARY**
Wording	"*should/should not be* offered"	"*may/may not be* offered"
Rationale	Known/anticipated advantages outweigh known/anticipated disadvantages ("should"), OR Known/Anticipated disadvantages outweigh known/anticipated advantages ("should not")	Known/anticipated advantages are closely balanced with known/anticipated disadvantages, OR uncertainty in the evidence of advantages and disadvantages exists
Implication	A strong recommendation applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present.	A discretionary recommendation may/may not be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable.

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LIST OF ABBREVIATIONS

Abbreviation	*Term*
Ad26	Modified human adenovirus 26
AE	Adverse event
AEFI	Adverse event following immunization
ARCHE	Alberta Research Center for Health Evidence
CDC	Centres for Disease Control and Prevention (United States)
ChAd	Chimpanzee Adenovirus
CI	Confidence interval
CIC	Canadian Immunization Committee
CIG	Canadian Immunization Guide
COVID-19	Coronavirus disease 2019
CVST	Cerebral venous sinus thrombosis
DART	Developmental and Reproductive Toxicity
DIC	Disseminated intravascular coagulation
EEFA	Ethics, Equity, Feasibility, and Acceptability
EMA	European Medicines Agency
FDA	Food and Drug Administration (US)
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	Human immunodeficiency virus
ICU	Intensive care unit
IM	Intramuscular
Ig	Immunoglobulin
IGRA	Interferon gamma release assay
JCVI	Joint Committee on Vaccination and Immunisation (UK)
MAAE	Medically attended adverse event
MenACWY	Quadrivalent meningococcal vaccine
mRNA	messenger ribonucleic acid
NACI	National Advisory Committee on Immunization
NITAG	National Immunization Technical Advisory Group
PCR	Polymerase chain reaction
PHAC	Public Health Agency of Canada
SAE	Serious adverse events
SAGE	Strategic Advisory Group of Experts on Immunization (WHO)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

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SD	Standard dose
SII	Serum Institute of India
SOC	System organ class
TST	Tuberculin skin test
TTS	Thrombosis with Thrombocytopenia Syndrome
UK	United Kingdom
US	United States
VIPIT	Vaccine-Induced Prothrombotic Immune Thrombocytopenia
VITT	Vaccine-Induced Thrombotic Thrombocytopenia
VOC	Variants of concern
VPD	Vaccine preventable disease
WHO	World Health Organization

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ACKNOWLEDGMENTS

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NACI gratefully acknowledges the contribution of: C Mauviel, K Ramotar, V Ferrante, S Pierre, E Tice, A Sinilaite, MW Yeung, L Whitmore, J Shurgold, J Vachon, J Macri, J Mielczarek, R Goddard, B Sader, M Patel, A House, and the Alberta Research Centre for Health Evidence, and the PHAC Public Health Ethics Consultative Group.

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APPENDIX A: EVIDENCE SUMMARY FOR PFIZER-BIONTECH COVID-19 VACCINE

Study C4591001 is the pivotal Phase 1/2/3 trial for the Pfizer-BioNTech COVID-19 vaccine. Evidence on immunogenicity is available for adults 18 to 55 and 65 to 85 years of age. Evidence on the safety and efficacy of the vaccine is available for adults 16 years of age and older. Studies did not include participants from long term care facilities. The Phase 2/3 portion of the trial involved approximately 44,000 study participants randomized (1:1) to receive either the vaccine or placebo. The data presented below are for an interim analysis, therefore the time of follow-up is not consistent but was less than four months after the second dose (maximum of 14 weeks) for all participants.

Evidence from the ongoing Phase 2/3 trial were published recently, after NACI's review of the evidence [37].

Efficacy

Severe outcomes due to COVID-19

There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, defined as laboratory-confirmed COVID-19 with one of the following additional features: clinical signs at rest that are indicative of severe systemic illness; respiratory failure; evidence of shock; significant acute renal, hepatic, or neurologic dysfunction; admission to an intensive care unit; or death [38].

There may be a protective effect against severe COVID-19 outcomes when receiving at least one dose of vaccine (overall vaccine efficacy of 88.9%, 95% CI: 20.1 to 99.7%), based on one case identified in the vaccine group (N=21,669) and nine cases in the placebo group (N=21,686). Vaccine efficacy against severe COVID-19 disease was also examined after receipt of Dose 2 (from 7 days and 14 days after Dose 2), but there were an insufficient number of events reported (one severe outcome in the vaccine group and three in the placebo group for each outcome) to determine whether the vaccine was efficacious in reducing severe outcomes with any precision (i.e., the resulting point estimates had wide confidence intervals that included zero).

Symptomatic COVID-19 disease

The estimated vaccine efficacy at least 7 days after Dose 2 was 94.6% (95% CI: 89.9 to 97.3%), with 9 confirmed symptomatic COVID-19 cases, as defined in trial protocol [37] identified among vaccine recipients (N=19,965) compared to 169 cases among placebo recipients (N=20,172). The vaccine efficacy at least 14 days after Dose 2 in this population was comparable (94.4%, 95% CI: 89.1 to 97.3%). Results were similar when estimating the efficacy specifically in individuals without evidence of prior SARS-CoV-2 infection at 95.0% (95% CI: 90.3 to 97.6%) with 8 confirmed cases among vaccine recipients (N=18,198) compared to 162 cases among placebo recipients (N=18,325).

When study participants without evidence of prior SARS-CoV-2 infection were stratified by age, vaccine efficacy against COVID-19 from 7 days after Dose 2 was between 93.7% (>55 years) and 95.6% (16 to 55 years). In individuals ≥65 years of age, vaccine efficacy was 94.7% (95% CI: 66.7 to 99.9%), while in participants ≥75 years of age, the observed vaccine efficacy was 100% compared to placebo, but with a wide confidence interval including zero which resulted from an insufficient number of events reported (0 vs 5 cases, 95% CI: –13.1 to 100.0%). The

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estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 91% (between 91.7% and 100.0%) in all subgroups stratified by "at risk" status (e.g., presence of a 1 or more comorbidities). The estimated vaccine efficacy against confirmed COVID-19 from 7 days after Dose 2 was greater than 89% for all races (89.3 to 100%) and 94% for all ethnicities included in the sub-analysis (94.4 to 95.4%).

After Dose 1, but prior to administration of Dose 2, 39 COVID-19 cases were identified in the vaccine group (n=21,669) compared to 82 in the placebo group (n=21,686) for an overall estimated vaccine efficacy of 52.4% (95% CI: 29.5 to 68.4%). If the analysis was restricted to cases identified only in the time period >14 days after dose 1 to before dose 2 the estimated vaccine efficacy increased to 92.3% (95% CI: 69 to 98%).

Table 7. Pfizer-BioNTech vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1[a]

Time period of interest	Events in vaccine group (N=21,669)	Events in placebo group (N=21,686)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1 to before dose 2	39	82	52.4% (29.5 to 68.4%)
>14 days after dose 1 to before dose 2[b]	2	27	92.3% (69 to 98%)

[a] In the all-available efficacy population consisting of randomized study participants who received at least one dose of the study intervention (i.e., vaccine or placebo)

[b] Comité sur l'immunisation du Québec. Stratégie de vaccination contre la COVID-19 : report de la 2e dose en contexte de pénurie. Institut national de Santé Publique du Québec, 18 décembre 2020

There is no analysis provided for efficacy specifically in individuals with prior evidence of SARS-CoV-2 infection.

Asymptomatic infection and transmission
There are no efficacy data for these outcomes at this time.

Immunogenicity

Humoral immune responses
Both SARS-CoV-2 binding and neutralizing antibodies induced by this vaccine had similar trends across both age groups studied (N=195). Maximal immune responses were seen on day 28, 7 days after the second dose. Binding and neutralizing antibodies were both induced by one dose of vaccine and boosted by the second dose of vaccine. The immune response elicited by one dose accounted for 10-20% of the maximal immune response. Up to day 35, older adults (65-85 years of age) had a lower immune response compared to younger adults (18-55 years of age). After the peak on day 28, immune responses decreased until the final evaluation point on day 52, 30 days after dose 2 in younger adults, while no decrease was observed in older adults. At all time points and age groups, immune responses were higher than placebo.

Cellular immune responses
Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine, as demonstrated by the increase in these cell population percentages from day 1 to day 28. Increases were seen in both younger adults (18-55 years of age) and older adults (65-85 years of age). The characterization of these cells indicates a Th-1 biased cellular immune response. Intermediate time points were not reported.

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Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 37,586 participants with a median of two months of follow-up (range: <2 weeks to <14 weeks) after Dose 2. About 19,000 participants had at least 2 months of follow-up, including about 9,500 who received the vaccine. Participants who inadvertently received the vaccine (n=12) or placebo (n=11) while pregnant are being followed.

Local Reactions

In vaccine recipients, frequency of local reactions was similar after Dose 1 and Dose 2. Pain at the injection site was very common (occurred in 66.1 to 83.1%, dependent on age and whether it was Dose 1 or Dose 2 administered). Most local reactions among vaccine recipients were mild or moderate in severity, with any severe reactions being reported by ≤0.6% of participants. No Grade 4 local reactions were reported. Across both age groups, local reactions after either dose had a median onset between zero and 2 days post-vaccination and a median duration of 1 to 2 days.

Systemic Reactions

Systemic events were generally increased in frequency and severity in vaccine recipients compared to placebo recipients, and in the younger age group (16-55 years old) compared with the older age group (≥56 years old), with frequencies and severity increasing with the number of doses (Dose 2 compared to Dose 1). Fatigue (34.1 to 59.4%), headache (25.2 to 51.7%), and muscle pain (13.9 to 37.3%) were very common in all age groups and after Dose 1 and Dose 2, respectively. Fever was common after the first dose (3.7% of 16-55 year olds, 1.4% of >55 year olds) but was very common after the second dose (15.8% of 16-55 year olds, 10.9% of >55 year olds). Joint pain was very common or common in all age groups (11.0 to 21.9% of 16-55 year olds, 8.6 to 18.9% of >55 year olds). Diarrhea was very common or common in both age groups (10.0 to 11.0% of 16-55 year olds, 8.0% of >55 year olds), but was similar to rates seen in the placebo group and did not appear to differ between Dose 1 and Dose 2.

Across age groups, the median onset day for most systemic events after either dose of vaccine was 1 to 2 days post-vaccination, with a median duration of 1 day. The majority of systemic events were mild or moderate in severity.

Overall, the frequency of any severe systemic event after Dose 1 was ≤0.9%. After Dose 2, severe systemic events had frequencies of <2% with the exception of fatigue (3.8%) and headache (2.0%). The proportion of participants that experience severe fever (>38.9°C to 40.0°C) increased between Dose 1 (0.2%) and Dose 2 (0.8%). Grade 4 fever (>40.0°C) was reported for 2 participants in each of the vaccine and placebo groups.

Severe or Serious Adverse Events

In total, 1.1% and 0.1% of participants in the vaccine group experienced at least one severe AE and one life-threatening adverse events (AE), respectively, compared to 0.7% and 0.1% of participants in the placebo group. There were no clinically meaningful differences in AEs by category observed by age, sex, or race/ethnicity.

The proportions of participants who reported at least 1 serious adverse event (SAE) were similar in the vaccine group (0.5%) and in the placebo group (0.4%). Three of the SAEs in the vaccine group and none in the placebo group were assessed by the investigator as related to study intervention: 1 SAE each of shoulder injury related to vaccine administration, ventricular arrhythmia, and lymphadenopathy. No clinically meaningful differences in SAEs were observed

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by age, sex, or race/ethnicity. After either vaccine dose, no participant reported an immediate allergic reaction to vaccine.

Other serious adverse events

Lymphadenopathy

Lymphadenopathy was not a solicited AE. Among participants (n=37,586) who were followed for <2 weeks to <14 weeks after Dose 2, AEs of lymphadenopathy were reported in 0.3% (n=64) participants (0.5% [n=54] in the younger age group and 0.1% [n=10] in the older age group) in the vaccine group and 6 participants (0.0%) in the placebo group. Among the AEs of lymphadenopathy in the vaccine group, the majority (47 of 64) were judged by the investigator as related to the vaccine. Most lymphadenopathy events were reported within 2 to 4 days after vaccination. The average duration of these events was approximately 10 days, with 11 events ongoing at the time of the data cut-off.

Appendicitis

Among participants who were followed <2 weeks to <14 weeks after Dose 2, there were a total of 12 participants with SAEs of appendicitis; 8 of which were in the vaccine group. Six of those 8 occurred in younger adults and 2 occurred in older adults. None of the cases were assessed as related to the vaccine by the investigators. The rate in either age group was not estimated to be greater than expected compared to baseline rates.

Death

There were 6 participants who died as of 14 November 2020, the data cut-off date for the interim analysis. This included 2 participants in the vaccine group and 4 participants in the placebo group. None of these deaths in the vaccinated group were assessed by the investigator as related to the vaccine.

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APPENDIX B: EVIDENCE SUMMARY FOR MODERNA COVID-19 VACCINE

Pivotal Phase 1, 2, and 3 trials are being conducted for the Moderna COVID-19 vaccine. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. Studies did not include participants from long term care facilities. The Phase 3 portion of the trial involved 30,413 study participants randomized (1:1) to receive either the vaccine (2 doses of 100 mcg) or placebo. The data presented below are for an interim analysis, therefore the time of follow-up is not consistent but was a median of two months after the second dose (maximum of 14 weeks) for all participants.

Efficacy

Severe outcomes due to COVID-19

There are no efficacy data for hospitalizations and deaths specifically, however data exists for efficacy against severe COVID-19 outcomes, as defined in the trial protocol [39]

The efficacy of the Moderna COVID-19 vaccine to protect against severe COVID-19 cases occurring at least 14 days after the second injection was in 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group). There were 30 confirmed severe COVID-19 cases in the placebo group compared to 0 cases in mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%).

Symptomatic COVID-19 disease

The primary efficacy outcome examined the efficacy of Moderna COVID-19 vaccine to protect against confirmed symptomatic COVID-19 starting 14 days after Dose 2 in study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline. This analysis included 28,207 study participants (14,073 participants in the placebo group and 14,134 participants in the Moderna COVID-19 vaccine group), with a median time of follow-up after receiving the second injection of 63 days. There were 185 confirmed COVID-19 cases [40] occurring at least 14 days after the second injection among placebo recipients compared to 11 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.1% (95% confidence interval, CI: 89.3 to 96.8%).

A subgroup analysis of the interim primary efficacy outcome was conducted in three age groups: 18 to <65 years of age (10,521 participants in the placebo group and 10,551 participants in the Moderna COVID-19 vaccine group), ≥65 years of age (3,552 participants in the placebo group and 3,583 participants in the Moderna COVID-19 vaccine group), and a further subgroup of study participants ≥75 years of age (688 participants in the placebo group and 630 participants in the Moderna COVID-19 vaccine group).

In study participants 18 to <65 years, there were 156 confirmed COVID-19 cases occurring at least 14 days after the second injection among placebo recipients compared to 7 cases among mRNA-1273 vaccine recipients, for an estimated vaccine efficacy of 95.6% (95% CI: 90.6 to 97.9%). The corresponding incidence rate per 1,000 person-years (total time at risk in each treatment group) was 64.63 in the placebo group and 2.88 in the Moderna COVID-19 vaccine group. In study participants ≥65 years of age there were 29 confirmed COVID-19 cases among placebo recipients compared to 4 cases among Moderna COVID-19 vaccine recipients, corresponding to a somewhat lower point estimate of vaccine efficacy of 86.4% (95% CI: 61.4

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to 95.2%). The corresponding incidence rate per 1,000 person-years was 33.73 in the placebo group and 4.60 in the Moderna COVID-19 vaccine group. In the subgroup of study participants ≥75 years of age there were 7 confirmed COVID-19 cases among placebo recipients compared to 0 cases among Moderna COVID-19 vaccine recipients, for a corresponding vaccine efficacy of 100.0% (95% CI: not evaluable to 100.0%), but this must be interpreted with caution as there were few events identified in this age group.

The efficacy of the Moderna COVID-19 vaccine to protect against confirmed COVID-19 cases occurring at least 14 days after the second injection was also assessed in participants most at risk for severe complications of COVID-19. In study participants 18 to <65 years of age and at risk for severe complications of COVID-19 (2,118 participants in the placebo group and 2,155 participants in the Moderna COVID-19 vaccine group) there were 35 confirmed COVID-19 cases in the placebo group compared to 2 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 94.4% (95% CI: 76.9 to 98.7%). In study participants 18 to <65 years of age, but not at risk for severe complications of COVID-19 (8,403 participants in the placebo group and 8,396 participants in the Moderna COVID-19 vaccine group) the estimated vaccine efficacy was 95.9% (95% CI: 90.0 to 98.3%) based on 121 confirmed COVID-19 cases in the placebo group and 5 cases among Moderna COVID-19 vaccine recipients. Vaccine efficacy estimates were also calculated for select individual co-morbid conditions; however, as of November 7, 2020 the number of identified events in these subgroups (n=0 to 11) were too small for meaningful analysis

A secondary analysis of vaccine efficacy to protect against the first occurrence of confirmed COVID-19 starting 14 days after Dose 2 regardless of prior SARS-CoV-2 infection, as determined by serologic titre, involved the full analysis set (randomly assigned study participants who received at least one injection). There were 30,351 study participants 18 years of age or older (15,170 participants in the placebo group and 15,181 participants in the Moderna COVID-19 vaccine group). There were 187 confirmed COVID-19 cases among placebo recipients compared to 12 cases among Moderna COVID-19 vaccine recipients, for an estimated vaccine efficacy of 93.6% (95% CI: 88.6 to 96.5%). However, there was a small proportion of study participants enrolled (n=679/29,148; 2.3%) with positive SARS-CoV-2 infection status at baseline.

In participants who had only received one dose of vaccine at the time of data analysis (placebo group: n=1,079; vaccine group: n=996), vaccine efficacy was 80.2% (95% CI: 55.2 to 92.5%). Limiting the analysis to 14 or more days after Dose 1, efficacy rose to 92.1% (95% CI: 68.8 to 99.1%). However, there are limited data on the efficacy of Dose 1 alone beyond 28 days post-vaccination.

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Table 8. Moderna vaccine efficacy against the first occurrence of symptomatic COVID-19 disease after dose 1[a]

Time period of interest	Events in vaccine group (N=996)	Events in placebo group (N=1,079)	Estimate of vaccine efficacy (95% confidence interval)
After dose 1	7	39	80.2% (55.2 to 92.5%)
>14 days after dose 1	2	28	92.1% (68.8 to 99.1%)

[a] In the modified intention-to-treat population consisting of randomized study participants who had received only one dose of their assigned intervention (i.e., vaccine or placebo) at the time of analysis

Asymptomatic infection and transmission

Nasopharyngeal swabs for SARS-CoV-2 virus were collected for all participants at specified intervals before Dose 1 and before Dose 2. There were 14 participants in the vaccine arm who were previously seronegative before administration of Dose 1 who had asymptomatic infection at the second time point, compared to 38 participants in the placebo arm. No formal efficacy data are available; however, assessment of this outcome is ongoing.

Immunogenicity

Humoral immune responses

Antibodies that bind the spike protein were induced in vaccine recipients by day 15 (15 days after dose 1) and reach maximum levels on day 43 (15 days after dose 2). Maximal binding antibody responses approximate the levels of the highest affinity samples of convalescent sera. Binding antibodies reached elevated levels on day 36 (7 days after dose 2) and persisted but decreased through day 119 (90 days after dose 2), the last day for which data is available.

Binding antibodies induced by 1 dose of the vaccine (i.e., on day 29) were 10-20% of the elevated responses seen on day 36. It is unknown how binding antibody responses change over time. Binding antibody responses through day 36 seems to be approximately equivalent across age groups. The data may suggest an age-dependent binding antibody durability. Antibody responses for age 70 or below decreased more slowly than for those above 70.

Neutralizing antibodies weren't induced to the level of convalescent sera until day 36, 7 days after dose 2 for all age groups. Neutralizing antibody responses through day 36 seems to be approximately equivalent across age groups. Neutralizing antibody responses on Day 119 represent a larger proportion of the maximum on day 43, compared to binding antibody responses. This may indicate increased durability of neutralizing antibody responses compared to binding antibody responses. These neutralizing data may also suggest an age-dependent neutralizing antibody durability as antibody responses on day 119 for each cohort were inversely proportional to the age of the cohort.

Immunogenicity data from the Phase 1 trial of the Moderna COVID-19 vaccine in a small number of subjects (n=33) demonstrate antibody persistence for 6 months [41].

Cellular immune responses

Both CD4+ and CD8+ T-cells specific to SARS-CoV-2 were induced by the vaccine. Maximal induction of both CD4+ and CD8+ T cells was observed on day 43, 14 days after dose 2. The percentage of CD8+T cells was lower for all age groups compared to CD4+ T cells. By comparing the percentage of cells that express Th-1 (IFN gamma, IL-2, TNF) vs. Th-2 (IL-4 and IL-13), it was demonstrated that this vaccine induces a Th1-biased cellular immune response.

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Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 30,351 participants with a median follow-up time of 63 days after Dose 2 (92 days after Dose 1). 23,276 participants had at least one month of follow-up after Dose 2 (12,021 individuals received the vaccine) and 7,667 individuals had at least 2 months of follow-up after Dose 2 (3894 individuals received the vaccine) [40]. Participants who inadvertently received the vaccine (n=6) or placebo (n=7) while pregnant are being followed.

Solicited Local Reactions

In vaccine recipients, frequency of local reactions increased from Dose 1 to Dose 2. Pain at the injection site was very common (occurred in 83.7% of vaccine recipients after Dose 1 and in 88.2% of vaccine recipients after Dose 2). Redness was common (2.8 to 8.6%) and swelling was common to very common (6.1 to 12.2%). Grade 3 (severe) reactions were reported by 3.5% and 7.0% of vaccine recipients after Dose 1 and Dose 2, respectively [40]. No Grade 4 local reactions were reported. The majority of local reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 3 days. Delayed injection-site reactions (i.e. with onset on day 8 or after) were noted in 0.8% of participants after the first dose and in 0.2% of participants after the second dose. Reactions were characterized by erythema, induration, and tenderness, and they resolved within 4 to 5 days.

Localized axillary swelling and tenderness was solicited and occurred in less than 5% of placebo recipients after any dose, and 10.2% and 14.2% of vaccine recipients after Dose 1 and 2, respectively. Among vaccine recipients, the incidence of severe (Grade 3) axillary swelling and tenderness increased from Dose 1 to Dose 2 (0.3 to 0.5%), whereas in the placebo group it decreased from Dose 1 to Dose 2 (0.2 to 0.1%) [40].

Solicited Systemic Reactions

Systemic events generally had a higher frequency and severity in vaccine recipients compared to placebo recipients, with frequency and severity increasing with the number of doses (Dose 1 compared to Dose 2). In vaccine recipients, fatigue (37.2 to 65.3%), headache (32.6 to 58.6%), muscle pain (22.7 to 58.0%), and arthralgia (16.6 to 42.8%) were very common in all age groups and after Dose 1 and Dose 2, respectively. Chills and nausea/vomiting were very common or common (8.3 to 44.2% and 8.3 to 19.0%, respectively). Fever was uncommon after the first dose (0.8%) but was very common after the second dose (15.5%).

Grade 3 reactions were reported by 2.9% and 15.7% of vaccine recipients after Dose 1 and Dose 2, respectively [40]. After Dose 2, Grade 3 fever (1.3%), headache (4.3%), fatigue (9.4%), myalgia (8.7%), arthralgia (5.1%), and chills (1.3%) were common. The proportion of vaccine recipients that experience Grade 3 fever (>38.9°C to 40.0°C) increased between Dose 1 (<0.1%; n=11) and Dose 2 (1.3%; n=202). Among placebo recipients only 2.7% reported Grade 3 adverse events after either dose.

The incidence of any Grade 4 events was <0.1% after both doses in both vaccine (6 to 12 events) and placebo (2 to 4 events) recipients. Grade 4 fever (>40.0°C) was reported for 4 placebo recipients and 4 vaccine recipients after Dose 1, and 2 placebo recipients and 12

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vaccine recipients after Dose 2. The majority of systemic reactions after either dose occurred within the first 1 to 2 days post-vaccination and had a median duration of 1 to 2 days.

Unsolicited Severe or Serious Adverse Events

During the first 28 days after any dose, 1.5% and 0.5% of participants in the vaccine group (Dose 1 and Dose 2, respectively) reported unsolicited severe and serious AEs (SAEs), compared to 1.3% and 0.6% of participants in the placebo group. There was no apparent effect of age on the relative incidence of SAEs in the vaccinated or placebo group.

Three SAEs in vaccinated individuals were considered by the study sponsor to be related to the trial intervention: two cases of facial swelling and one case of nausea and vomiting with headaches and fever.

Four additional SAEs in vaccine recipients and five SAEs in placebo recipients were considered to be related to the trial intervention by trial investigators [40]. Of the SAEs considered related to the Moderna vaccine, 2 cases of autoimmune diseases were reported: one rheumatoid arthritis in a participant known with hypothyroidism, that was unresolved at the time of the report and one autonomic dysfunction in a participant known with hypothyroidism, also unresolved at the time of the report. In the placebo group, one participant (known to have chronic back pain) developed polymyalgia rheumatica, which was resolving.

No clinically meaningful differences in SAEs were observed by age. Sex and race/ethnicity were not assessed. After either vaccine dose, no participant in the Phase 3 study reported an immediate allergic reaction to vaccine.

Other serious adverse events

Facial swelling

Two female participants with a history of dermal filler injection in the cheeks experienced facial swelling 1 to 2 days following immunization. Both were treated and the swelling resolved after a duration of about 5 days. A third female participant with a history of dermal filler injection in the lips had lip angioedema 2 days after vaccination which was classified as medically significant but not considered as an SAE. The management and duration of this third event were not specified.

Death

A total of 13 deaths were reported, 6 in the vaccine group and 7 in the placebo group. None of these deaths were assessed to be related to any study intervention or COVID-19.

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APPENDIX C: EVIDENCE SUMMARY FOR ASTRAZENECA COVID-19 VACCINE

Results from four clinical trials (two Phase 1/2, one Phase 2/3, and one Phase 3) were available at time of authorization for the AstraZeneca COVID-19 vaccine. Results from an ongoing Phase 3 trial in the United States (US) are not available at time of writing. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. The Phase 2/3 trial (COV002) trial and Phase 3 trial (COV003) assessed efficacy, safety and immunogenicity of the vaccine. The Phase 2/3 trial was based in the United Kingdom, (UK) while the Phase 3 trial was based in Brazil. These two studies underwent a series of protocol amendments and logistical challenges during the conduct of the trials that resulted in significant changes to the trials' methodology. There were changes from a single to a two-dose vaccine regimen, the use of both a low dose/standard dose (LD/SD) (in COV002 only, due to dosing error) and standard dose/standard dose (SD/SD) vaccine regimen, and the recruitment of progressively older study participants (56–69 and then ≥70 years of age) after the initial focus on adults 18–55 years of age. In the SD/SD vaccine regimen, study participants were randomized (1:1) to receive either the AstraZeneca COVID-19 vaccine, AZD1222 (5×10^{10} viral particles per 0.5 mL dose) or control injection. The participants randomized to the control group were administered two doses of quadrivalent meningococcal vaccine (MenACWY) (COV002) or MenACWY for Dose 1 and placebo for Dose 2 (COV003).

There were significant differences in the baseline characteristics of participants in the Phase 2/3 and Phase 3 trials. In addition, the clinical trials prioritized the recruitment of health care professionals and other adults with high potential for exposure to SARS-CoV-2, including health care and social setting workers.

Evidence from the AstraZeneca COVID-19 vaccine trials has been published [42].

Efficacy

The estimates of vaccine efficacy for the AstraZeneca COVID-19 vaccine (AZD1222) come from the Phase 2/3 and Phase 3 trials. As of a data cut-off date of November 4, 2020 the primary analysis population (study participants who received either the LD/SD or SD/SD regimens) for the primary outcome included 11,636 participants seronegative at baseline (5,807 in the vaccine group, 5,829 in the control group). Of this population, 8,895 study participants (4,440 vaccine recipients and 4,455 controls) received the SD/SD regimen. As of a data cut-off date of December 7, 2020, the SD/SD population had increased to include 12,158 study participants (6,085 vaccine recipients and 6,073 controls). Unless otherwise noted, all data presented in this summary is based on the SD/SD vaccine regimen and as of a data cut-off date of December 7, 2020.

Symptomatic COVID-19 disease

The primary efficacy outcome assessed in the two trials was prevention of the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2, based on assessments of cases by an Adjudication Committee blinded to participant group assignment, and analysed in the combined LD/SD and SD/SD regimen population. Assessment in the subgroup that only received SD/SD was a pre-specified secondary analysis in the clinical trial. Symptomatic COVID-19 was defined as having at least one of the following symptoms (objective fever ≥37.8 C, cough, shortness of breath, and anosmia or ageusia) AND a swab positive for SARS-CoV-2 by RT-PCR AND confirmed by an Adjudication Committee.

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Based on data as of December 7, 2020, there were 12,158 study participants 18 years of age or older without prior evidence of SARS-CoV-2 infection at baseline (6,085 vaccine recipients and 6,073 controls) included as part of the SD/SD regimen analysis. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants receiving the SD/SD vaccine regimen was 62.5% (95% CI: 50.7 to 71.4%), based on identification of 71/6,085 (1.2%) cases in vaccine recipients and 186/6,073 (3.1%) in controls. The estimated vaccine efficacy by age was 63.1% (51.1 to 72.1%) in study participants 18-64 years of age and 50.7% (-65.8 to 85.4%) in participants ≥65 years of age. An ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18–55 years of age who received the SD/SD dosing regimen. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 59.3% (95% CI: 25.1 to 77.9%) in this age group. This analysis included study participants with any interval duration between doses.

Symptomatic COVID-19 by interval

As of December 7, 2020, the majority of study participants in the COV002 (UK) and COV003 (Brazil) clinical trials received the two doses of the SD/SD regimen within a 4–8 week (UK: 45.6%, Brazil: 87.2%) or a 9–12-week interval (UK: 34.4%; Brazil: 10.5%). About 1 in 5 study participants in the UK clinical trial (18.9%) received the SD/SD regimen with a >12-week interval between vaccine doses, and in the Brazil trial it was less than 1 in 50 study participants (1.8%). A very small proportion of study participants received the SD/SD regimen with a <4-week interval between doses (UK: 1.0%, Brazil: 0.4%).

An exploratory analysis examined the potential effect of the interval between the administration of the first and second vaccine doses on vaccine efficacy in study participants receiving the SD/SD vaccine regimen. Table 9 summarizes the estimates of vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 by dosing interval. There is a suggestion of an increase in the point estimate of vaccine efficacy with increasing intervals between the first and second dose of vaccine. However, it is important to note that the confidence intervals around these point estimates overlap.

Table 9. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after Dose 2 in all participants, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks	67/5,473 (1.2)	162/5,422 (3.0)	59.6% (46.4 to 69.6%)
4 – 8 weeks	52/4,188 (1.2)	113/4,098 (2.8)	55.7% (38.5 to 68.1%)
9–12 weeks	15/1,285 (1.2)	49/1,324 (3.7)	69.0% (44.8 to 82.6%)
>12 weeks	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

In a subgroup analysis in study participants who received the SD/SD vaccine regimen, vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after dose 2 was estimated by dosing interval and age group. These ad-hoc subgroup analyses were performed in participants 18-55 years of age from the COV002 (UK) clinical trial and in all study participants who received the SD/SD regimen (from COV002 and COV003), dichotomized into groups 18–64 years and ≥65 years of age.

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The ad-hoc subgroup analysis performed to examine the potential confounding effect of age and dosing interval on estimates of vaccine efficacy in the COV002 (UK) clinical trial generated an estimate of vaccine efficacy in study participants 18-55 years of age who received the SD/SD regimen at an interval of >8 weeks between doses. Based on the interim data as of November 4, 2020, this subgroup analysis found an estimated vaccine efficacy of 65.6% (95% CI: 24.5 to 84.4%). In the updated dataset as of December 7, 2020, there were 1,375 study participants ≥65 years of age (699 in the vaccine group and 676 in the control group). Efficacy estimates for participants ≥65 years for the overall 4–12-week dosing interval and the 4–8-week interval have wide confidence intervals that include zero. Estimates of vaccine efficacy could not be calculated for participants ≥65 years for the 9–12-week and >12-week dosing intervals due to a lack of older study participants who received the SD/SD regimen during these dosing intervals (Table 10).

Table 10. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning ≥15 days after dose 2, by dosing interval and age group (SD/SD seronegative baseline efficacy set[a])

Dosing interval and age group	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
4–12 weeks			
18–64 years	63/4,790 (1.2)	156/4,760 (3.0)	60.5% (47.1 to 70.5%)
≥65 years	4/683 (0.6)	6/662 (0.9)	43.2% (-99.3 to 83.8%)
4 – 8 weeks			
18–64 years	48/3,506 (1.4)	107/3,439 (3.1)	56.6% (39.1 to 69.1%)
≥65 years	4/682 (0.6)	6/659 (0.9)	43.4% (-98.5 to 83.9%)
9–12 weeks			
18–64 years	15/1,284 (1.2)	49/1,321 (3.7)	69.0% (44.8 to 82.6%)
≥65 years	0/1 (0)	0/3 (0)	No estimate
>12 weeks			
18–64 years	4/571 (0.7)	22/599 (3.7)	81.6% (47.0 to 93.6%)
≥65 years	0/0 (0)	0/0 (0)	No estimate

[a]Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Symptomatic COVID-19 by presence of co-morbidity

Efficacy was also assessed based on the presence of comorbidity, which was defined as the presence of one or more of the following mild to moderate and controlled medical conditions at baseline: cardiovascular disease, respiratory disease, diabetes, or obesity (BMI ≥30 kg/m^2) based on a data cut-off date of November 4, 2020. For this exploratory analysis, included study participants who were SARS-CoV-2 seronegative at baseline and received the SD/SD regimen. The estimated vaccine efficacy against confirmed COVID-19 cases occurring at ≥15 days after Dose 2 in study participants without comorbidities was 58.0% (95% CI: 25.8 to 76.2%), based on 17/2,825 (0.6%) cases identified in the vaccine group compared to 39/2,774 (1.4%) cases in the control group. The corresponding estimate of vaccine efficacy in study participants with comorbidities was 67.1% (95% CI: 33.2 to 83.8%), based on the identification of 10/1,611 (0.6%) cases in the vaccine group compared to 32/1,670 (1.9%) cases in the control group.

Symptomatic COVID-19 after one dose

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Efficacy at various time points after one dose of AstraZeneca COVID-19 vaccine was assessed as a secondary/exploratory analysis based on data as of the interim analysis cut-off date of November 4, 2020 (Table 11). The analysis involved study participants who were SARS-CoV-2 seronegative at baseline and received SD vaccine as their initial vaccine dose. The median duration of follow-up after Dose 1 was 115 days (range: 41–149 days). Note that approximately 80% of study participants in the vaccine arm received the second dose of the vaccine; therefore, several estimates of vaccine efficacy are not solely due to the one dose of SD vaccine.

Table 11. Estimates of vaccine efficacy against the first occurrence of confirmed COVID-19 beginning after Dose 1, (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Events in vaccine group (AZD1222)	Events in control group (MenACWY)	Estimate of vaccine efficacy (95% confidence interval)
After Dose 1	92 (N=8,008)	185 (N=8,013)	50.5% (36.5 to 61.5%)
≥22 days after Dose 1	51 (N=6,307)	141 (N=6,297)	64.1% (50.5 to 73.9%).
≥22 after Dose 1 but before Dose 2	15 (N=6,310)	52 (N=6,296)	71.3% (49.0 to 83.8%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)

Severe outcomes due to COVID-19

Severe COVID-19 disease

Severe COVID-19 disease, defined as study participants who met the confirmed COVID-19 case definition and were assigned a severity score of ≥6 on the World Health Organization Clinical Progression Scale (e.g., clinical severity requiring hospitalization, and may include intubation and mechanical ventilation, and death), was assessed as a secondary analysis of vaccine efficacy. Analysis included study participants who had been followed for ≥15 days since Dose 2, who were seronegative for SARS-CoV-2 at baseline, and received both doses of the SD/SD regimen. As of December 7, 2020, there were 6,085 study participants in the vaccine group and 6,073 participants in the control group. There was 1 case of severe COVID-19 disease identified in a study participant in the control group who received the control intervention within the 4–12-week dosing interval. This participant also required ICU admission and eventually died. An additional severe case occurred >21 days after the first dose and ≤14 days after the second dose in a study participant in the control group.

Hospitalizations

Vaccine efficacy against COVID-19 associated hospitalizations was assessed at multiple time points (Table 12). Assessment included study participants who were seronegative for SARS-CoV-2 at baseline and received both doses of the SD/SD regimen. After Dose 2 (median follow-up duration: 36 days, range: 1–79 days, based on data as of November 4, 2020), there were 7 hospitalizations due to COVID-19 identified in study participants who received the SD/SD regimen within the 4–12-week dosing interval, all in participants in the control group. There were no hospitalizations in the vaccine group ≥22 days after Dose 1; however, there were 2 cases hospitalized due to COVID-19 identified in the vaccine group and 16 in the control group ≥15 days after Dose 1, resulting in an estimate of vaccine efficacy of 87.6% (95% CI: 46.0 to 97.2%). The 2 hospitalizations in the vaccine group were 1 and 10 days post vaccination (median follow up: 115 days, range: 41–149).

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Table 12. Estimates of vaccine efficacy against hospitalization, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Time period of interest	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]	0/6,307 (0.0)	9/6,297 (0.1)	100% (95% CI: 49.6 to NE)
≥15 days after Dose 2[c]	0/6,085 (0.0)	7/6,073 (0.1)	N/A

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

Deaths

As of the updated data cut-off date of December 7, 2020, there has been a single death due to COVID-19 identified in a study participant in the control group.

Asymptomatic infection and transmission

This was an exploratory analysis conducted only in clinical trial COV002 (UK). As part of the study protocol, beginning one week after receipt of Dose 1, study participants were asked to provide weekly self-administered nose or throat swabs for RT-PCR testing. Participants were asked to report symptoms when they appeared; however, the presence or absence of symptoms at the time of sample collection was not routinely collected. An asymptomatic infection was defined as a study participant with a swab virologically confirmed for SARS-CoV-2 and who reported no clinical trial–defined symptoms of confirmed COVID-19. Study participants with virologically confirmed SARS-CoV-2 infection, but who did not report whether or not they had symptoms were classified as "unknown symptoms".

Table 13. Estimates of vaccine efficacy against asymptomatic infection, by dosing interval (SD/SD seronegative baseline efficacy set[a])

Dosing interval	Event in vaccine group (AZD1222) n/N (%)	Events in control group (MenACWY) n/N (%)	Vaccine efficacy (95% CI)
≥22 days after Dose 1[b]			
	14/3,060 (0.5%)	15/3,064 (0.5%)	6.6% (-93.5 to 54.9%)
≥15 days after Dose 2[c]			
Any interval	8/2,377 (0.3%)	11/2,340 (0.5%)	26.9% (-81.5 to 70.6%)
4–12 weeks	N/A	N/A	37.7% (-90.1 to 79.6%)
>12 weeks	N/A	N/A	-4.3% (-416.5 to 79.0%)

[a] Participants without prior evidence of SARS-CoV-2 infection at baseline; all SD/SD vaccine recipients (or respective controls)
[b] Based on data as of November 4, 2020
[c] Based on data as of December 7, 2020

An additional ad-hoc analysis combining study participants with SARS-CoV-2 asymptomatic infection or associated with unknown symptoms also failed to demonstrate the efficacy of the SD/SD regimen (3.9%, 95% CI: -72.1 to 46.4%), based on the identification of 22 cases in the vaccine group and 23 cases in the control group ≥15 days after Dose 2.

Immunogenicity

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Approximately 15% of the overall safety analysis set was targeted for inclusion in the immunogenicity analysis set. These analyses combined evidence from SD/SD and LD/SD dosing regimens, and may not completely align with the data from individual studies.

Humoral immune responses

Antibody responses, both binding and neutralizing, differed for seronegative and seropositive vaccine recipients. Vaccine recipients who were seropositive at baseline demonstrated high antibody titres 28 days after Dose 1 compared to seronegative recipients. Seronegative recipients demonstrated an increase in their immune responses 28 days after Dose 2. By contrast, seropositive recipients had decreased immune responses after Dose 2 compared to responses after Dose 1. However, immune responses for seropositive recipients at all time points were higher than those for seronegative recipients. The mechanism behind these differences, and their potential impact on vaccine efficacy and effectiveness remains unclear. A recently published article contains additional evidence on humoral responses [30].

Antibody responses, both binding and neutralizing, were lower in older adults (65+) than in younger adults after both the first and second dose of vaccine. Without a correlate of protection, the significance of these difference in antibody responses is unclear.

Cellular immune responses

Cellular immune responses were elicited by this vaccine. The first dose elicited Th-1 biased CD4+ T cells in both younger and older age groups. Younger vaccine recipients exhibited higher cellular immune responses than older age groups. Notably, the second vaccine dose did not augment cellular immune responses. The mechanism and the impact on vaccine efficacy and effectiveness remains unclear.

Anti-Vector immune responses

It is unclear to what extent pre-existing immunity to any adenovirus-based vaccine vector exists in the Canadian population and what impact that could have on adenovirus based vaccine safety and efficacy. It is also unclear as to what extent immunization with adenovirus-based vaccines elicits anti-vector immune responses and what impact that could have on homologous or heterologous booster doses with adenovirus-based vaccines. Evidence for a viral vector vaccine based on human adenovirus 5 (not authorized in Canada) indicated that vaccine recipients with high pre-existing immunity to the adenovirus vector had lower anti-SARS-CoV-2 immune responses [43]. The AstraZeneca COVID-19 vaccine uses a modified chimpanzee adenovirus vector (ChAd). AstraZeneca found no correlation between anti-ChAd neutralizing antibody responses and anti-SARS-CoV-2 immune responses. It also found that neutralizing antibody levels were not boosted after receiving the second dose. However, neutralization is not the only anti-vector immune response that could impact vaccine-induced immunity. It remains unclear if immune responses to the ChAd vector will impact the efficacy or effectiveness of this vaccine.

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Vaccine Safety and Adverse Events Following Immunization

Safety evidence is based on interim analyses of 23,745 participants of which 12021 received at least one dose of the AZ COVID-19 vaccine and 11724 received a control. The safety analyses were conducted in different analysis sets. Solicited adverse events occurring within 7 days after any dose were assessed among 2648 vaccine recipients who received at least one dose (SD) and 2497 control recipients. Approximately one third of study participants received their second vaccine dose within 6 weeks of receiving Dose 1. The majority (~90%) of study participants in the safety cohort were less than 65 years of age. The median duration of follow-up was 105 days post-Dose 1 and 62 days post-Dose 2.

Solicited Local Reactions

Solicited local injection site AEs were reported by 74.7% of evaluated participants within the first 7 days following any vaccine dose. Pain and tenderness were most frequently reported (54.2% and 63.7%, respectively) followed by warmth (17.7%), bruising (17.3%), redness (14.0%), pruritus (12.7%), and swelling (10.0%). The majority of solicited local reactions among vaccine recipients were mild or moderate in severity, with any grade 3 or 4 reactions being reported by ≤9.5% of participants. No Grade 4 AEs were reported. Local reactions were generally milder and reported less frequently after the second dose of the vaccine. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose within 6 weeks following Dose 1 (38.0% versus 58.3% to 74.3% when Dose 2 was provided after ≥6 weeks).

Solicited Systemic Reactions

Solicited systemic AEs were reported by 73.0% of evaluated participants within the first 7 days following any vaccine dose. The most common systemic solicited systemic AEs were fatigue (53.1%) and headache (52.6%). Other frequently reported systemic solicited AEs were muscle pain (44.0%), malaise (44.2%), feverishness (33.6%), chills (31.9%), joint pain (26.4%), nausea (21.9%) and fever ≥38.0°C (7.9%). Overall, the frequency of any grade 3 or 4 reaction was ≤8.3%. The single reported Grade 4 event was fever > 40°C. Across study groups, AEs were milder and reported less frequently after the second vaccine dose. By dose interval, the reactogenicity of the vaccine was lower in participants who received the second dose at <6 weeks following Dose 1 (37.6% versus. 49.2% to 67.1% when Dose 2 was provided after at ≥6 weeks).

Unsolicited Serious Adverse Events

SAE were reported by less than 1% of study participants and was similar between the vaccine and control groups (0.7% and 0.8%, respectively). There were no clear imbalances by System Organ Class (SOC). The most frequently reported SAEs by SOC were 'Infections and Infestations' (0.1% vs 0.2%) and 'Injury, poisoning and procedural complications' (<0.1% vs 0.1%).

Two SAEs (pyrexia, transverse myelitis) in the vaccine recipients were considered related to the vaccine by the study investigators. The case of pyrexia (40.5°) occurred 2 days after dose 1 and resolved the same day following the administration of acetaminophen. The event of transverse myelitis occurred in a 37-year-old female with a family history of Charcot-Marie-Tooth type 1a (mother and brother). The participant received two doses of study intervention 77 days apart. Two weeks after the second dose, the participant developed sensory changes and clumsiness. Magnetic resonance imaging showed a lesion consistent with transverse myelitis or anterior spinal infarction. A third SAE was originally identified (C-reactive protein increase); However,

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after the cut-off date, causality for the SAE of C-reactive protein increase was updated by the investigator to be not treatment related.

Other serious adverse events

Demyelinating events
An event of multiple sclerosis occurred in a 37-year-old female who developed sensory symptoms about 10 days after first (and only) vaccination. The clinical episode had a duration of 3 weeks. Further follow up with MRI of spine and brain showed an acute spinal lesion and older cerebral lesions, revealing pre-existing, but previously unrecognized, multiple sclerosis.

Death
A total of 6 deaths were reported among study participants (2 in the vaccine group and 4 in the control group). The cause of death among vaccine recipients included malignant neoplasm and fungal pneumonia, with neither considered to be related to the study intervention by the investigators.

Vaccine-Induced Immune Thrombotic Thrombocytopenia
Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been reported in Canada and globally following post-licensure use of AstraZeneca COVID-19 vaccine. Cases have have usually occurred between 4 and 28 days after receipt of vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the viral vector COVID-19 vaccines may trigger VITT is still under investigation. At this time, no other predisposing factors have consistently been identified in patients who develop VITT. The rate of this adverse event is still to be confirmed but is most commonly estimated to be between 1 in 100,000 and 1 in 250,000 persons vaccinated with the AstraZeneca COVID-19 vaccine; The rate of VITT in Canada as of April 28, 2021 is closer to 1 per 100,000 persons vaccinated with the AstraZeneca/Covishield COVID-19 vaccine. Additional information is currently being gathered to characterize the rate of VITT more accurately. Based on available information, the case fatality of VITT typically ranges between 25 and 40%. Case fatality may vary with increased awareness of the adverse event and appropriate early treatment.

Effectiveness in individuals ≥65 years of age

In the absence of sufficient data from clinical trials to date on the efficacy of the AstraZeneca COVID-19 vaccine in those 65 years of age and older, a review of three observational studies in the UK published as pre-prints on real-world vaccine effectiveness in this age group has been conducted to inform NACI's recommendations in this age group. The findings of this review are summarized below.

All three observational studies assessed one dose of either the Pfizer-BioNTech or the AstraZeneca vaccines in the United Kingdom. The results below pertain only to the AstraZeneca portion of the studies. The studies were conducted during the period when SARS-CoV-2 B.1.1.7 variant was rapidly becoming the dominant circulating strain in their respective geographic regions. Approximately 50% of laboratory samples were found to have a profile consistent with the B.1.1.7 variant in early December, 2020 in England, and 43% in Scotland in early January, 2021. By mid to late February, the SARS-CoV-2 B.1.1.7 variant

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represented almost 100% of circulating strains in England, and was considered the dominant strain in Scotland.

Overall summary of evidence:

In adults 65 years of age and over, observational data available from pre-prints from the United Kingdom have shown a reduction in the risk of symptomatic disease and hospitalization starting from two weeks following one dose of AstraZeneca vaccine.

Detailed summary of each study:

1. Hyams et al., Assessing the Effectiveness of BNT162b2 and ChAdOx1nCoV-19 COVID-19 Vaccination in Prevention of Hospitalisations in Elderly and Frail Adults: A Single Centre Test Negative Case-Control Study. SSRN-Lancet **preprint.** March 3, 2021. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3796835

Description: Test-negative case control study of hospitalized people ≥80 years of age (many of whom were frail with comorbidities) in two hospitals in Bristol, United Kingdom. Vaccination was determined by record linkage and adjustment was conducted for a number of factors. Vaccine effectiveness against hospitalization was assessed in those who had been vaccinated ≥14 days before symptom onset.

Results: One-dose vaccine effectiveness of 80.4% (95% CI: 36.4 – 94.5) against hospitalization occurring within 14 or more days (maximum 53 days) after one dose of AstraZeneca COVID-19 vaccine among patients ≥80 years of age.

Review:

- Vaccination was determined by record linkage and clinical information was obtained from records by individuals who are blinded to the participants SARS-CoV-2 results. These are methodological strengths of this study.
- The authors performed a sensitivity analysis of those with symptom onset < 14 days after vaccination and did not find an effect, which is expected as this is too early for the vaccine to work, and adds strength to differences they note 14 days or more after vaccination.
- Eligible cases and controls were selected from the medical admission list, and it is unclear how this was done.
- Separate analyses seemed to have been conducted for AstraZeneca and Pfizer-BioNTech but it is unclear how the study subjects for each analysis were assigned.

2. Lopez Bernal et al., Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. medRxiv. **Preprint** March 2, 2021. https://www.medrxiv.org/content/10.1101/2021.03.01.21252652v1

Description: Test negative-case control study using linked surveillance data in the United Kingdom among patients ≥70 years of age. PCR tests were within 10 days of onset of symptoms. For those who were vaccinated, cases and controls were assessed by time since

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vaccination to onset of symptoms, controlling for a number of factors. The impact of vaccination on hospitalization in individuals ≥80 years of age was also assessed in those who tested positive

Results: One-dose vaccine effectiveness against symptomatic PCR confirmed SARS-CoV-2 infection in the adjusted analysis was 22% (95% CI: 11 – 32) 14 to 20 days after vaccination and gradually rose up to 73% (95% CI: 27 – 90) 35 or more days (maximum 48 days) after vaccination. As well as the effect against symptomatic disease, in individuals who were ≥80 years of age there was an additional 37% protection against hospitalization within 14 days of a positive test in those 14 or more days from their first dose of vaccine compared to those who were unvaccinated.

Review:

- Record linkage using large data sets is a strength of this study.
- A relatively small number of subjects were included in the AstraZeneca COVID-19 vaccine analysis at later time periods, particularly in the time period of 35 or more days after vaccination when the vaccine effectiveness was the highest.
- The unadjusted and adjusted odds ratio are considerably different in the AstraZeneca COVID-19 analysis reflecting differences between study groups.
- Demographic and clinical information for cases and controls and vaccinated and unvaccinated individuals were not provided.

3. Vasileiou et al. Effectiveness of first dose COVID-19 vaccines against hospital admissions in Scotland effectiveness findings from Scotland: national prospective cohort study of 5.4 million people. SSRN-Lancet **preprint.** February 19, 2021. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789264

Description: A prospective observational cohort study using record linkage between databases, including vaccination, hospitalization and laboratory records for the population in Scotland, with adjustment for a number of factors. Although the study included those ≥18 years of age, the AstraZeneca vaccine was mostly administered to participants aged 65 years and older. Age-specific vaccine effectiveness is provided but did not distinguish between the Pfizer-BioNTech and AstraZeneca vaccines, which were both studied, although those ≥80 years of age mainly received the AstraZeneca vaccine.

Results: The effectiveness of one dose of the AstraZeneca vaccine against hospitalization was 74% (95% CI: 66 – 81) 14 to 20 days after vaccination and rose up to 94% (95% CI: 73 – 99) 28 to 34 days after vaccination. In patients ≥80 years of age, the authors found a peak vaccine effectiveness (VE) of 81% (95% CI: 65 – 90) against hospitalization within 28 to 34 days after one dose of vaccine that was mainly the AstraZeneca vaccine.

Review:

Due to concerns with methodological weaknesses in this study, NACI did not use these results to inform its recommendations. Methodological weaknesses include:

- AstraZeneca COVID-19 vaccine effectiveness against hospitalization was high (70%) 7 to 13 days after vaccination, which is biologically implausible, as 7 to 13 days would be too early to expect protection from infection or hospitalization as a result of vaccination, suggesting methodological concerns and making the high vaccine effectiveness results at later time periods (94% at 28 to 34 days) challenging to interpret.

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- The number of people vaccinated with the AstraZeneca COVID-19 vaccine is small in the period 28 days and more from vaccination.
- As vaccine roll out was initially tailored to priority groups at higher risk of severe disease or exposure, adjustments for potential confounding factors conducted during the statistical analyses might not have adequately controlled for all the differences between vaccinated and unvaccinated individuals. Demographic and risk factor comparisons between vaccinated and unvaccinated groups were not provided separately for each vaccine.
- Hospital admission was defined as: COVID-19 as the main cause of admission or hospitalization within 28 days of a positive PCR SARS-CoV-2 test. Hospital admission for COVID-19 is a less specific criteria for determining COVID-19 hospitalization and the proportion of cases defined using that criteria are not provided.
- Although product specific vaccine effectiveness and age specific vaccine effectiveness are both provided separately, product specific vaccine effectiveness by age was not provided.
- Record linkage using large data sets is a strength of this study.

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APPENDIX D: EVIDENCE SUMMARY FOR JANSSEN COVID-19 VACCINE

Data from Phase 1, 2, and 3 trials were available at the time of authorization for the Janssen vaccine. Evidence on efficacy, immunogenicity, and safety is available for adults ≥18 years of age. The Phase 3 trial involved 44,325 study participants randomized (1:1) to receive either the vaccine (1 dose of 5×10^{10} viral particles) or placebo. The data presented below was a median of two months after the completion of the series (one dose).

Efficacy

Symptomatic COVID-19 disease

Estimates of efficacy against moderate to severe/critical COVID-19 disease was the primary outcome for the Phase 3 trial. Due to the relatively broad definition of moderate COVID-19 disease adopted for the clinical trial, less than 1% of identified cases met the mild COVID-19 case definition. Therefore, nearly all observed symptomatic COVID-19 cases are captured by the definition of moderate to severe/critical COVID-19.

The co-primary endpoints for the efficacy analysis of the vaccine are the prevention of the first occurrence of confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 post-vaccination and with onset ≥28 days post-vaccination. The primary analysis is supported by subgroup analyses of the primary endpoints stratified by study country, age group, the presence of comorbidities associated with an increased risk of progression to severe COVID-19 disease, sex, and by race/ethnicity. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 and ≥28 days post-vaccination are secondary endpoints, also supported by analyses stratified by the same subgroups as the primary endpoint. Additional analyses of efficacy in cases with severe/critical COVID-19 include examinations by cases requiring medical intervention, hospitalizations and deaths. For both the primary and secondary endpoints, cumulative incidence curves are used to examine the potential onset and duration of vaccine efficacy. Exploratory analyses of vaccine efficacy against asymptomatic or undetected SARS-CoV-2 infection, symptom severity and viral load are also investigated. Select outcomes from these analyses are presented in this Appendix.

A number of the analyses are conducted in the full analysis set, defined as study participants who were randomized and received the study intervention (vaccine or placebo), regardless of the occurrence of protocol deviations or serostatus at baseline. However, most primary efficacy analyses are conducted in the per-protocol set, defined as study participants who were randomized, received the study intervention (vaccine or placebo), were seronegative at the time of vaccination, and had no major protocol deviations that were judged to possibly impact the efficacy of the vaccine. Many of the subgroup analyses are conducted in the per-protocol set using centrally confirmed COVID-19 cases, but repeated using a larger dataset consisting of both centrally confirmed cases and cases with a positive PCR result from a local testing site that had not yet been confirmed by the central clinical trial testing facility at the date of data cut-off for the analysis. The use of the locally confirmed cases is supported by the demonstration of a high concordance (90.3%) in PCR results between local and central clinical trial testing facilities. **Unless otherwise specified, all efficacy analyses presented in this summary are in the per-protocol set of study participants based on a January 22, 2021 data cut-off date.**

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Confirmed symptomatic moderate to severe/critical COVID-19 infection

The definition of moderate COVID-19 disease used in the clinical trial was very broad and so cases meeting the moderate to severe/critical case definition constituted >99% of all identified symptomatic COVID-19 in the trial. The estimates of vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onsets ≥14 days and ≥28 days post-vaccination are 66.9% and 66.1%, respectively (Table 14).

Table 14. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, per-protocol set

Co-Primary outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
Moderate and severe/critical COVID-19 infection	116/19,514	3,116.6	348/19,544	3,096.1	66.9% (59.0 to 73.4)
≥28 days post-vaccination					
Moderate and severe/critical COVID-19 infection	66/19,306	3,102.0	193/19,178	3,070.7	66.1% (55.0 to 74.8)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Tables 5 and 6

Confirmed symptomatic severe/critical COVID-19 infection

The estimates of vaccine efficacy against confirmed symptomatic severe/critical COVID-19 infection are 76.7% with onset ≥14 days post-vaccination and 85.4% with onset ≥28 days post-vaccination (Table 15).

Table 15. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, per-protocol set

Co-Primary outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
Severe/critical COVID-19 infection	14/19,514	3,125.1	60/19,544	3,122.0	76.7% (54.6 to 89.1)
≥28 days post-vaccination					
Severe/critical COVID-19 infection	5/19,306	3,106.2	34/19,178	3,082.6	85.4% (54.2 to 96.9)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Tables 5 and 6

Subgroup analyses

By study country

The time period of the clinical trial was associated with the emergence of new SARS-CoV-2 VOC in some study countries. At the time of data cut-off for the primary analysis, preliminary genetic sequencing data were available for a proportion of case isolates from Brazil, South

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Africa and the US (Table 16). No SARS-CoV-2 variants from the B.1.1.7 or P.1 lineages were detected in any of the sequenced isolates.

Table 16. Genetic sequencing results for VOC, September–December, 2020

Country	Cases identified N	Cases sequenced n (%)	Sequencing Results
Brazil	179	124 (69.2)	86/124 (69.4%) – variant 20J/501Y.V3 of the of the P.2 lineage 38/124 (30.6%) – Wuhan-Hu1 reference sequence+D614G
South Africa	136	91 (66.9)	86/91 (94.5%) – variant 20H/501Y.V2 of the B.1.351 lineage
United States	268	197 (73.5)	190/197 (96.4%) – Wuhan-Hu1 reference sequence+D614G

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Section 4.1.3.1. Epidemiologic Setting of the Study

Analyses of vaccine efficacy by country were conducted in countries with >100 identified cases (US, 247; Brazil, 153; and South Africa, 133) using a dataset consisting of both centrally PCR-confirmed COVID-19 cases and cases with a positive PCR result from in-country testing not yet confirmed by the central clinical trial testing facility at the data cut-off date for the analysis. The rationale for inclusion of the locally confirmed cases was demonstration of a high concordance (90.3%) in PCR results between local and central clinical trial testing facilities. The point estimates of vaccine efficacy by country against both confirmed symptomatic moderate to severe/critical COVID-19 and severe/critical COVID-19 with onset ≥14 days and ≥28 days post-vaccination are comparable to or greater than the overall estimates of efficacy at these time points (Table 17). The one exception is the point estimate of efficacy for South Africa at ≥14 days post-vaccination.

Table 17. Efficacy against confirmed symptomatic moderate to severe/critical and severe/critical COVID-19, by country for countries with greater than 100 moderate to severe/critical cases, centrally and in-country PCR-confirmed cases

Country	Onset post-vaccination	COVID-19 severity	
		Moderate to severe/critical Efficacy (95% CI)	Severe/critical Efficacy (95% CI)
US	≥14 days	74.4% (65.0 to 81.6)	78.0% (33.1 to 94.6)
	≥28 days	72.0% (58.2 to 81.7)	85.9% (-9.4 to 99.7)
Brazil	≥14 days	66.2% (51.0 to 77.1)	81.9% (17.0 to 98.1)
	≥28 days	68.1% (48.8 to 80.7)	87.6% (7.8 to 99.7)
South Africa	≥14 days	52.0% (30.3 to 67.4)	73.1% (40.0 to 89.4)
	≥28 days	64.0% (41.2 to 78.7)	81.7% (46.2 to 95.4)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 11

By age group

Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination was assessed in a variety of age groups (Table 18).

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Table 18. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by age group, per-protocol set

Age group (years)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
18–39	47/4,356	775.3	122/4,330	762.1	62.1% (46.6 to 73.6)
40–59	48/8,394	1,331.5	138/8,452	1,332.9	65.2% (51.3 to 75.5)
60–69	19/4,800	722.9	65/4,907	732.2	70.4% (50.0 to 83.2)
70–79	2/1,768	259.5	23/1,650	239.2	92.0% (67.6 to 99.1)
≥80	0/196	27.42	0/205	29.8	N/A*
<60 (i.e., 18–59)	95/12,750	2,106.8	260/12,782	2,095.0	63.7% (53.9 to 71.6)
<65 (i.e., 18–64)	107/15,544	2,530.3	297/15,552	2,511.2	64.2% (55.3 to 71.6)
≥60	21/6,764	1,009.8	88/6,762	1,001.2	76.3% (61.6 to 86.0)
≥65	9/3,970	586.3	51/3,992	584.9	82.4% (63.9 to 92.4)
≥75	0/751	88.4	8/690	99.2	100.0% (45.9 to 100.0)
≥28 days post-vaccination					
18–39	29/4,316	772.4	84/4,254	756.6	66.2% (47.9 to 78.6)
40–59	23/8,301	1,325.2	68/8,273	1,320.4	66.3% (45.2 to 80.0)
60–69	12/4,749	719.3	32/4,833	727.1	62.1% (24.4 to 82.2)
70–79	2/1,746	257.8	9/1,620	237.2	79.6% (1.2 to 97.9)
≥80	0/194	27.3	0/198	29.3	N/A
<60 (i.e., 18–59)	52/12,617	2,097.6	152/12,527	2,077.0	66.1% (53.3 to 75.8)
<65 (i.e., 18–64)	60/15,378	2,518.7	170/15,253	2,490.1	65.1% (52.9 to 74.5)
≥60	14/6,689	1,004.4	41/6,651	993.6	66.2% (36.7 to 83.0)
≥65	6/3,928	583.3	23/3,925	580.5	74.0% (34.4 to 91.4)
≥75	0/740	106.4	3/673	98.1	N/A

*N/A = Not available; estimates of vaccine efficacy not calculated when there were fewer than 6 events identified.
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 30 and 31

The efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination was calculated for four age groups: 18–59, 18–64, ≥60, and ≥65 years of age (Table 19).

The analysis was repeated using the larger dataset of both confirmed COVID-19 cases and cases with a positive PCR result from a local, in-country testing site. The estimates of vaccine efficacy in participants ≥65 years of age at ≥14 days and ≥28 days post-vaccination increased to 71.4% and 70.1%, respectively.

Table 19. Efficacy against confirmed symptomatic severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by age group, per-protocol set

Age group (years)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥14 days post-vaccination					
18–59	8/12,750	2,114.3	41/12,782	2,115.1	80.5% (57.8 to 92.1)
18–64	11/15,544	2,538.5	50/15,552	2,533.8	78.0% (57.3 to 89.7)
≥60	6/6,764	1,010.7	19/6,762	1,006.9	68.5% (18.1 to 89.7)
≥65	3/3,970	586.6	10/3,992	588.3	69.9% (-16.8 to 94.7)
≥28 days post-vaccination					
18–59	2/12,617	2,101.0	24/12,527	2,086.7	91.7% (66.7 to 99.1)
18–64	2/15,378	2,522.8	28/15,253	2,500.9	92.9% (71.9 to 99.2)
≥60	3/6,689	1,005.1	10/6,651	995.9	70.3% (-15.5 to 94.7)
≥65	3/3,928	583.4	6/3,925	581.7	50.1% (-133.4 to 91.9)

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Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 32 and 33

By comorbidity

In the clinical trial, the presence of comorbidities was defined as a study participant with one or more medical conditions at baseline that were associated with an increased risk of progression to severe COVID-19 disease (e.g., asthma, cerebrovascular disease, hypertension, respiratory disease, liver disease, and obesity). In participants with and without comorbidities, efficacy was assessed against confirmed symptomatic moderate to severe/critical and against severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination (Table 20).

A repeat of the analysis using the larger dataset of both centrally and locally in-country confirmed COVID-19 cases estimated vaccine efficacy against (a) moderate to severe/critical COVID-19 infection and (b) against severe/critical COVID-19 infection in participants with comorbidities of 58.6% (95% CI: 40.6 to 71.6%) and 75.2% (95% CI: 32.0 to 92.7%) with onset ≥28 days post-vaccination.

Table 20. Efficacy against confirmed symptomatic (a) moderate to severe/critical and (b) severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, by presence or absence of comorbidities, per-protocol set

Presence of comorbidities (yes/no)	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
(a) Moderate to severe/critical COVID-19 infection					
≥14 days post-vaccination					
Yes	47/7,777	1,140.0	126/7,798	1,133.7	62.9% (47.8 to 74.1)
No	69/11,737	1976.6	222/11,746	1,962.5	69.1% (59.4 to 76.8)
≥28 days post-vaccination					
Yes	27/7,684	1,133.6	52/7,626	1,121.7	48.6% (16.7 to 69.0)
No	39/11,622	1,968.4	141/11,552	1,949.0	72.6% (60.7 to 81.3)
(b) Severe/critical COVID-19 infection					
≥14 days post-vaccination					
Yes	8/7,777	1,142.9	29/7,798	1,141.7	72.4% (38.2 to 89.1)
No	6/11,737	1,982.1	31/11,746	1,980.3	80.7% (53.0 to 93.4)
≥28 days post-vaccination					
Yes	4/7,684	1,135.0	12/7,626	1,124.2	67.0% (-8.9 to 92.2)
No	1/11,622	1,971.1	22/11,552	1,958.3	95.5% (72.1 to 99.9)

Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Figures 30, 31, 32 and 33

By serostatus

This analysis was conducted using the expanded dataset of both centrally and locally confirmed COVID-19 cases and estimated vaccine efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection in study participants based on serostatus at baseline (Table 21).

Table 21. Efficacy against confirmed symptomatic moderate to severe/critical COVID-19 infection with onset ≥14 days and ≥28 days post-vaccination, including confirmed and non-centrally confirmed cases, by serostatus, per-protocol set

Baseline SARS-CoV-2 serostatus	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	

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≥14 days post-vaccination					
Regardless of baseline status	176/21,636	3,450.2	513/21,574	3,409.8	66.1% (59.7 to 71.6%)
Positive	3/2,122	336.3	4/2,030	320.8	28.5% (-322.8 to 89.5)
Negative	173/19,514	3,113.9	509/19,544	3,089.1	66.3% (59.9 to 71.8)
≥28 days post-vaccination					
Regardless of baseline status	114/21,424	3,436.3	326/21,199	3,385.9	65.5% (57.2 to 72.4)
Positive	1/2,118	336.1	2/2,021	320.0	N/A*
Negative	113/19,306	3,100.3	324/19,178	3,065.9	65.5% (57.2 to 72.4)

*N/A = Not available; estimates of vaccine efficacy not calculated when there were fewer than 6 events identified.
Source: Table 14, FDA Briefing document for Vaccines and Related Biological Products Advisory Committee meeting (February 26, 2021)

Hospitalizations

A post-hoc analysis assessed vaccine efficacy against COVID-19 associated hospitalizations. The analysis was performed for cases with onset ≥1 day, ≥14 days and ≥28 days post-vaccination in study participants seronegative at baseline (Table 22). At each time point, the analysis was performed using (a) centrally confirmed COVID-19 cases only, and (b) both centrally and locally confirmed cases ("Any positive PCR result").

Table 22. Efficacy against COVID-19 associated hospitalizations with onset ≥1, ≥14 and ≥28 days post-vaccination

Analysis population	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
≥1 day post-vaccination (in FAS-SN)					
Confirmed cases	6	3,202.8	18	3,213.1	66.6% (12.1 to 89.1)
Any positive PCR result	6	3,202.8	42	3,211.6	85.7% (66.1 to 95.0)
≥14 days post-vaccination (PP)					
Confirmed cases	2	3,125.8	11	3,125.9	81.8% (16.7 to 98.0)
Any positive PCR result	2	3,125.8	29	3,125.1	93.1% (72.7 to 99.2)
≥28 days post-vaccination (PP)					
Confirmed cases	0	3,106.3	6	3,084.4	100.0% (15.7 to 100.0)
Any positive PCR result	0	3,106.3	16	3,083.9	100.0% (74.3 to 100.0)

FAS-SN = Full analysis set, all randomized study participants with documented study vaccine administration, seronegative at baseline; PP = per-protocol set
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 10

Deaths

There were 19 deaths reported during the clinical trial: 3 in the vaccine group and 16 in the placebo group. Of the 19 deaths, zero in the vaccine group were determined to be associated with COVID-19, based on WHO COVID-19 case classifications combined with a positive RT-PCR result, compared to 5 COVID-19 associated deaths in the placebo group. All 5 deaths in the placebo group were in South African study participants with one or more comorbidities with an increased risk for progression to severe COVID-19 disease.

Asymptomatic or undetected SARS-CoV-2 infection

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Analysis of vaccine efficacy against asymptomatic or undetected COVID-19 infection (study participants not meeting one of the case definitions for symptomatic COVID-19 and with a positive PCR or serology result) and against seroconversion were conducted at two time points: with onset 1 to 29 days and ≥28 days post-vaccination. A sensitivity analysis was also performed for each of these outcomes by removing participants with symptoms at any time since screening and prior to the positive PCR or serology result("without previous symptoms").

The point estimate of vaccine efficacy against asymptomatic or undetected COVID-19 infection with onset ≥28 days post-vaccination is 59.7% (and 74.0% after removal of participants with prior symptoms) and against seroconversion it is 66.5% (74.2% with removal of participants with prior symptoms) (Table 23). The seroconversion results should be interpreted with caution as this is a preliminary analysis based on a limited duration of follow-up in approximately 29% of study participants planned for the final analysis based on Day 71 serology.

Table 23. Efficacy against asymptomatic and undetected COVID-19 infection, and against seroconversion, with onset ≥28 days post-vaccination

Outcomes	Vaccine group		Placebo group		Vaccine efficacy (95% CI)
	Cases (n/N)	Person years	Cases (n/N)	Person years	
Full analysis set, seronegative at baseline					
Asymptomatic or undetected SARS-CoV-2 infection	22/19,301	3,099.7	54/19,162	3,064.2	59.7% (32.8 to 76.6)
Asymptomatic or undetected SARS-CoV-2 infection *without previous symptoms*	10/19,301	3,098.0	38/19,162	3,061.5	74.0% (46.8 to 88.4)
Serology risk set*					
Seroconverted	18/1,346	312.2	50/1,304	298.2	65.5% (39.9 to 81.1)
Seroconverted *without previous symptoms*	10/1,346	310.9	37/1,304	296.6	74.2% (47.1 to 88.6)

*Serology risk set = study participants with a serology result available at Day 71 post-vaccination
Source: Janssen manufacturer submission to Health Canada, Module 2.5: Clinical overview, Table 12

Immunogenicity

The majority of the immunogenicity analysis is based on data from a Phase 1 trial that included 2 cohorts of healthy adults aged 18 to 55 and ≥65 years of age. Within each cohort, there were two dose levels given as one or two doses. The analysis below is from one dose of the lower dose, $5x10^{10}$ viral particles.

Humoral immune responses

Antibody responses were elicited by one dose of the Janssen vaccine. Binding and neutralizing antibodies reached a maximum by day 29 and maintained through day 85 (last time point of evaluation) in the younger cohort. In the older cohort, binding antibody responses were slightly lower than those in the younger cohort and were elicited more slowly, increasing from day 15 through day 57 (last time point of evaluation). Neutralizing antibody responses were similar levels to those in the younger cohort, elicited by day 15 and maintained an approximate plateau through day 57. Functional antibody responses as determined through Fc effector function were maximally elicited by day 29 (the last day of evaluation), at similar levels in both age cohorts.

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Minimal data are available for seropositive vaccine recipients that may suggest that they respond strongly to one dose of vaccine.

Minimal data are also available demonstrating decreased neutralizing antibody responses to viral variant B.1.1.7.

Without a correlate of protection, the significance of these difference in antibody responses is unclear.

Cellular immune responses
Cellular immune responses were elicited by one dose of this vaccine and were similar in both age cohorts. Spike protein-specific CD4+ T cells responses were detected in 76% of younger vaccine recipients and 60% of older vaccine recipients. Th-1 biased CD4+ T cell responses were observed by day 15 post-vaccination and remained elevated until day 29 (last time point of evaluation). Spike protein-specific CD8+ T cells responses were detected in 51% of younger vaccine recipients and 36% of older vaccine recipients by day 15 post vaccination and remained elevated until day 29.

Anti-vector immune responses
It is unclear to what extent pre-existing immunity to any adenovirus-based vaccine vector exists in the Canadian population and what impact that could have on adenovirus based vaccine safety and efficacy. It is also unclear as to what extent immunization with adenovirus-based vaccines elicits anti-vector immune responses and what impact that could have on homologous or heterologous booster doses with adenovirus-based vaccines. Evidence for a COVID-19 viral vector vaccine based on human adenovirus 5 (not authorized in Canada) indicated that vaccine recipients with high pre-existing immunity to the adenovirus vector had lower anti-SARS-CoV-2 immune responses[43] The Janssen COVID-19 vaccine uses a modified Ad26. Janssen found no correlation between anti-Ad26 neutralizing antibody responses and anti-SARS-CoV-2 immune responses. However, neutralization is not the only anti-vector immune response that could impact vaccine-induced immunity. It remains unclear if immune responses to the Ad26 vector will impact the efficacy or effectiveness of this vaccine.

Vaccine safety and adverse events following immunization

Safety evidence is based on interim analyses of 21,895 participants (of whom 7,331 were ≥60 years of age) who received at least one dose of the vaccine. A safety subset included 3,356 participants in the vaccine group who were followed for solicited reactions within 7 days following vaccination and unsolicited reactions within 28 days following vaccination. Medically attended adverse events (MAAEs), SAEs and AEs leading to discontinuation from study participation were assessed in all participants. Overall, the median duration of follow-up was 58 days after vaccination.

Solicited local reactions
Solicited local injection site AEs were reported by 50.3% of evaluated participants within the first 7 days following any vaccine dose. Injection site pain was the most frequently reported local AE (48.7%) followed by warmth (7.3%) and swelling (5.3%). In the vaccine group, the frequency of solicited local AEs was lower in participants aged ≥60 years compared to participants aged ≥18 to <60 years. The frequency of solicited local AEs was also similar in participants who were seronegative for SARS-CoV-2 at baseline compared to participants who were seropositive for

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SARS-CoV-2 at baseline (50.1% and 54.5%, respectively). The majority of solicited local reactions among vaccine recipients were mild or moderate in severity, with any Grade 3 reactions being reported by ≤0.7% of participants. No Grade 4 solicited local AEs were reported.

Solicited systemic reactions

Solicited systemic AEs were reported by 55.2% of evaluated participants within the first 7 days following vaccine administration. The most common systemic solicited AEs were headache (39.0%) and fatigue (38.3%). Other frequently reported systemic solicited AEs were muscle pain (33.2%), nausea (14.2%) and fever ≥38.0°C (9.0%). While AEs were lower in participants aged ≥60 years compared to participants aged ≥18 to <60 years, there were no clinically relevant differences in the frequency of solicited systemic AEs. AEs were similarly observed in participants who were seronegative for SARS-CoV-2 at baseline (55.4%) compared to participants who were seropositive for SARS-CoV-2 at baseline (50.6%). Overall, the frequency of any Grade 3 reactions was <2%, and no Grade 4 solicited systemic AEs were reported. Antipyretics were recommended post-vaccination for symptom relief as needed. Analgesics or antipyretics were used by 26.4% of vaccinated 18 to 59 year olds and 9.8% of vaccinated individuals 60 years of age and older up to 7 days post vaccination in the full analysis. The majority of solicited systemic AEs were transient in nature and had a median duration of 1 to 2 days after vaccination.

Unsolicited serious adverse events

During the 28-day period post-vaccination, there were 19 (0.6%) participants with unsolicited AEs of at least Grade 3 in the vaccine group compared to 18 (0.6%) participants in the placebo group. Of these unsolicited AEs of at least Grade 3, 5 (0.1%) were considered to be related to the study vaccine. There were no clear imbalances by System Organ Class (SOC). No cases of anaphylaxis were identified in the clinical trials. However, the manufacturer announced receipt of preliminary reports of two cases of severe allergic reactions, including one case of anaphylaxis, in participants who had received the vaccine. Details on the reports have not been provided to date.

In total there were 7 (<0.1%) participants who reported SAEs that were considered to be related to the study vaccine by the investigator and lead to discontinuation from the study. These included:

- Grade 4 Guillain-Barré syndrome in a participant 16 days after vaccination. The case was considered indeterminate as per WHO AEFI criteria; however, due to close temporal association and lack of other explanatory factors, it was considered as possibly related to the vaccine for reporting purposes.
- Grade 4 pericarditis in a participant approximately 17 days following vaccination and resulted in hospitalization. The event was assessed as indeterminate as per WHO AEFI criteria; however, due to close temporal association and a lack of other explanatory factors it was assessed as possibly related to the vaccine for reporting purposes.
- Grade 3 brachial radiculitis in a participant with immediate onset following vaccination.
- Grade 3 post-vaccination syndrome 2 days following vaccination. Based on the symptoms, the event was assessed as vaccine reactogenicity (asthenia).
- Grade 3 Type IV hypersensitivity in a participant 3 days following vaccination. The case was considered likely related to vaccination due to close temporal association.
- Grade 2 facial paralysis (Bell's Palsy) in two participants 3 and 16 days after vaccination. Both events were assessed to have an inconsistent causal association with immunization, per the WHO AEFI criteria.

Other serious adverse events

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Tinnitus

Six cases of tinnitus were reported in the vaccine group and none in the placebo group. All cases were considered non-serious, and two cases were considered related by the investigator. All participants had underlying medical conditions (such as history of tinnitus and migraine, history of hypertension, seasonal allergies and hypothyroidism) or used medications that offered a more plausible alternative cause for the event compared to the vaccine.

Convulsions/seizures

Four cases were reported in the vaccine group (1 serious) and one case (non-serious) in the placebo group, all of which were considered not related to the study vaccine by the investigator. The serious case of convulsion/seizure was reported in a participant with a history of epilepsy and obsessive-compulsive disorder.

Thrombotic and thromboembolic events

The overall incidence of thrombotic and thromboembolic events (arterial and venous) was similar across the vaccine (n=15, 0.1%) and placebo groups (n=10, <0.1%). A numerical imbalance was observed for the deep vein thrombosis deep/ pulmonary embolism subtypes, with a total of 9 cases in the vaccine group (4 serious) and 3 cases in the placebo group (2 serious). One case of transverse sinus thrombosis occurred on Day 21 following vaccination in a 25-year-old male participant with no past medical history. The participant also presented a seizure reported to be a consequence of a secondary bleed caused by elevated venous pressure from the venous flow obstruction. Two thrombectomy procedures were performed because of the participant's hypercoagulable state. No clear cause of the event was identified and it was deemed unrelated to the vaccine as there were possible contributing factors (preceding infection and anatomical anomaly). One non-serious case with onset 27 days after vaccination in a participant with a medical history of obesity and cholecystectomy was considered to be related to the vaccine.

Vaccine-Induced Immune Thrombotic Thrombocytopenia

Rare cases of serious blood clots, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been recently reported in the United States following post-licensure use of Janssen COVID-19 vaccine. This adverse event is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) and has been associated with both the AstraZeneca and Janssen COVID-19 viral vector vaccines. The mechanism of action is similar to heparin-induced thrombocytopenia (HIT). The exact mechanism by which the viral vector COVID-19 vaccines may trigger VITT is still under investigation. As of April 28, 2021, 17 cases of VITT out of 8 million doses of Janssen administered in the United States have been confirmed. Most of the cases to date have occurred in females between the ages of 18 and 59 years, however investigations are ongoing and additional cases may be indentified with increased awareness and current emphasis on the clinical recognition of this event. Reports indicated symptom onset between 6 and 15 days after vaccination. Investigations are ongoing.

Demyelinating disorders

In total there were four cases of demyelinating disorders that were reported in the vaccine group (2 cases peripheral neuropathy, 1 benign monoclonal hypergammaglobulinemia, 1 Guillain-Barré syndrome) compared with 5 cases in the placebo group (2 cases peripheral neuropathy, 1 Guillain-Barré syndrome and 2 sensory loss.

Death

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A total of 19 deaths were reported among study participants (3 in the vaccine group and 16 in the control group). In the vaccine group, causes of death by preferred term were lung abscess, non-COVID-19 pneumonia, and 1 of unknown cause at the time of data cut-off. None of these deaths were considered to be related to the study intervention by the investigators.

Pregnancies

Eight pregnancies were reported through January 22, 2021 (4 vaccine, 4 placebo). Vaccination was within 30 days after last menstrual period in 7 participants (3 vaccine, 4 placebo) while in 1 vaccine recipient vaccination was prior to last menstrual period. Unsolicited AEs related to pregnancy included spontaneous abortion (1 vaccine, 0 placebo), incomplete abortion (0 vaccine, 1 placebo), elective abortion (0 vaccine, 2 placebo) and ectopic pregnancy (1 vaccine, 0 placebo). Two pregnancies are ongoing among participants in the vaccine group, with unknown outcomes at this time.

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APPENDIX E: FREQUENCY OF SOLICITED ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 VACCINES IN CLINICAL TRIALS

Table 24. Frequency of solicited local adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine				Moderna COVID-19 Vaccine			
	Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	NS	NS	NS	NS	NS	NS	NS	NS
Redness/erythema	Common	Common	Common	Rare	Common	Common	Uncommon	Uncommon
Swelling	Common	Common	Rare	Rare	Common	Very Common	Uncommon	Uncommon
Lymphadenopathy[b]/ Axillary swelling and tenderness	NS	NS	NS	NS	Very Common	Very Common	Common	Common
Warmth	NS	NS	NS	NS	NS	NS	NS	NS
Pruritis	NS	NS	NS	NS	NS	NS	NS	NS
Induration	NS	NS	NS	NS	NS	NS	NS	NS

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Lymphadenopathy was not a solicited adverse event for the Pfizer BioNTech COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix A for more details.

Table 25. Frequency of solicited local adverse events in authorized populations for viral vector COVID-19 vaccines[a]

AEFI	AstraZeneca COVID-19 Vaccine				Janssen COVID-19 Vaccine[b]	
	Vaccine		MenACWY control		Vaccine	Placebo control
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	Very Common	Very Common	Very Common	Very Common	NS	NS
Redness/erythema	Very Common	Common	Common	Uncommon	Common	Common

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Swelling	Common	Common	Common	Common	Common	Common
Lymphadenopathy[c]/ Axillary swelling and tenderness	NS	NS	NS	NS	NS	NS
Warmth	Very Common	Common	Very Common	Common	NS	NS
Pruritis	Very Common	Common	Common	Common	NS	NS
Induration	Common	Common	Common	Common	NS	NS

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Single dose vaccine (dose 2 not applicable)

[c] Lymphadenopathy was not a solicited adverse event for the AstraZeneca COVID-19 vaccine and was reported as an unsolicited adverse event. Please see Appendix C for more details.

Table 26. Frequency of solicited systemic adverse events in authorized populations for mRNA COVID-19 vaccines[a]

AEFI	Pfizer-BioNTech COVID-19 Vaccine				Moderna COVID-19 Vaccine			
	Vaccine		Placebo control		Vaccine		Placebo control	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Very Common	Common	Common	Common	Very Common	Common	Common
Joint Pain	Common	Very Common	Common	Common	Very Common	Very Common	Very Common	Very Common
Fever[b]	Common	Very Common	Uncommon	Uncommon	Uncommon	Very Common	Uncommon	Uncommon
Feverishness[b]	NS	NS	NS	NS	NS	NS	NS	NS
Diarrhea	Common	Common	Common	Common	NS	NS	NS	NS
Nausea and/or Vomiting[c]	Uncommon	Common	Uncommon	Uncommon	Common	Very Common	Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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Table 27. Frequency of solicited systemic adverse events in authorized populations for viral vector COVID-19 vaccines[a]

AEFI	AstraZeneca COVID-19 Vaccine				Janssen COVID-19 Vaccine[b]	
	Vaccine		MenACWY control		Vaccine	Placebo control
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle Pain	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Common	Common	Common	NS	NS
Joint Pain	Very Common	Very Common	Common	Common	NS	NS
Fever[c]	Common	Common	Uncommon	Uncommon	Common	Uncommon
Feverishness[c]	Very Common	Common	Common	Common	NS	NS
Diarrhea	NS	NS	NS	NS	NS	NS
Nausea and/or Vomiting[d]	Very Common/ Common	Common/ Uncommon	Very Common/ Uncommon	Common/ Uncommon	Very Common	Common

Abbreviations: AEFI: adverse event following immunization; MenACWY: Quadrivalent meningococcal vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients

[b] Single dose vaccine (dose 2 not applicable)

[c] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[d] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

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APPENDIX F: BENEFIT-RISK ASSESSMENT FOR THE USE OF VIRAL VECTOR COVID-19 VACCINES IN A PUBLIC HEALTH CONTEXT

A benefit-risk analysis was conducted to determine whether the benefit of earlier vaccination with each of the viral vector vaccines ((instead of waiting for a later age-based mRNA vaccine) outweighed the risk of harms from Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). In this analysis, the possible benefits were defined as potential intensive care unit (ICU) admissions and deaths due to COVID-19 that could occur while waiting for a later mRNA vaccine, that could be prevented with the use of an immediate viral vector vaccine (AstraZeneca or Janssen COVID-19 vaccine. The potential harm was the development of VITT events requiring ICU admission and/or resulting in death. An age-based analysis was conducted to account for differences in risk for COVID-19 disease and development of severe outcomes by age.

Methodology

The approach to the benefit-risk analysis was based on the analysis conducted by the UK Winton Centre for Risk and Evidence Communication, using Canadian data where available.

Calculation of potentially prevented COVID-19 ICU admissions and death

Five scenarios were considered, with daily COVID-19 case incidence rates per 10,000 corresponding to very low to high activity levels in the national COVID-19 Activity Levels Framework. These daily rates were then converted to weekly incidence rates (see Table 28). A very high activity level was assumed to be double the high activity level. Analysis for the AstraZeneca COVID-19 vaccine was completed between April 16 and 21, 2021. Analysis for the Janssen COVID-19 vaccine was completed on April 26, 2021.

The weekly number of expected cases (per 100,000) of ICU admission and deaths due to COVID-19 were calculated by applying the age distribution of cases reported in Canadian surveillance data (cumulative to April 9, 2021) in 10-year age bands from 20 to 69 years of age against the weekly COVID-19 incidence defined by the five scenarios in Table 18. We applied the reported age-specific proportion of cases that were hospitalized, hospitalized cases that were admitted to ICU, and cases who died (see Table 29) to the weekly incidence rates. We assumed a single dose vaccine effectiveness of 80% against severe outcomes for both viral vector vaccines.

In the context of the anticipated vaccine supply in Canada, the total number of events potentially prevented were calculated by multiplying the number of weekly events by the number of weeks each age group was estimated to have to wait before being able to receive an mRNA vaccine (see Table 30).

Calculation of potential VITT cases

To assess the potential harm of receiving each viral vector vaccine, we assumed a fixed rate of VITT events across age groups due to limited available information on age-based risk. Given the uncertainty on the incidence of VITT events, we assessed scenarios with a rate of 1 case per 250,000 vaccine doses administered and 1 case per 100,000 doses administered for the AstraZeneca vaccine, and

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1 case per 500,000, 1 case per 250,000, and 1 case per 100,000 doses administered for the Janssen vaccine, where 100% of cases would require ICU admission. When comparing mortality due to COVID-19 and mortality due to VITT, we considered two scenarios for the AstraZeneca COVID-19 vaccine, assuming that 25% or 40% of VITT cases died to account for the current uncertainty. For the Janssen COVID-19 vaccine, we assumed 20% of VITT cases died. Rates of VITT and deaths were based on currently observed rates for both vaccines. In the case on Janssen, higher VITT rates were also assessed to determine the impact on benefit-risk if the VITT rate becomes similar to that observed after administration of AstraZeneca vaccine.

Table 28. Daily and weekly incidence rates of infection under five different scenarios used for benefit-risk analysis

Scenario	Daily incidence per 10,000	Weekly incidence per 100,000
Very low	0.06	4.20
Low	0.30	21.00
Moderate	0.75	52.50
High	3.00	210.00
Very high[a]	6.00	420.00

[a] The very high scenario was considered for the purposes of this benefit-risk analysis only, and is not based on a category of activity within the COVID-19 Activity Levels Framework

Table 29. Proportion of COVID-19 events of interest by age group based on Canadian surveillance data

Age Group	Distribution of cases	Proportion of cases who are hospitalized	Proportion of hospitalized cases who require ICU care	Proportion of cases who die
20 to 29	18.80%	0.94%	13.83%	0.02%
30 to 39	16.10%	1.79%	15.61%	0.05%
40 to 49	14.65%	2.69%	20.91%	0.13%
50 to 59	13.33%	4.99%	25.06%	0.47%
60 to 69	8.40%	10.62%	27.17%	2.15%

Table 30: Projected wait time to mRNA vaccines used in analyses based on anticipated supply of mRNA vaccines

Age Group	Projected wait time (weeks) for AstraZeneca vaccine analysis[a]	Projected wait time (weeks) for Janssen vaccine analysis[b]

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20 to 29	7	5
30 to 39	6	4
40 to 49	4	2
50 to 59	3	1
60 to 69	1	0

[a] Calculated April 16, 2021
[b] Calculated April 26, 2021

Results

Benefit-risk analysis for the AstraZeneca COVID-19 vaccine

Table 31. Expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.04	0.21	0.53[a]	2.12[a]	4.24[a]
30 to 39	0.40	0.07	0.33	0.82[a]	3.29[a]	6.58[a]
40 to 49	0.40	0.09	0.43[a]	1.08[a]	4.32[a]	8.64[a]
50 to 59	0.40	0.12	0.60[a]	1.50[a]	6.01[a]	12.03[a]
60 to 69	0.40	0.07	0.33	0.83[a]	3.32[a]	6.64[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.
[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 32. Expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.04	0.21	0.53	2.12[a]	4.24[a]
30 to 39	1.00	0.07	0.33	0.82	3.29[a]	6.58[a]
40 to 49	1.00	0.09	0.43	1.08[a]	4.32[a]	8.64[a]

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50 to 59	1.00	0.12	0.60	1.50[a]	6.01[a]	12.03[a]
60 to 69	1.00	0.07	0.33	0.83	3.32[a]	6.64[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 33. Expected VITT deaths by age group (based on VITT rate of 1 per 250,000) compared to expected deaths due to COVID-19 prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios

Age Group	Expected deaths due to VITT per 100,000		Scenario activity level (daily incidence of reported COVID-19 cases)				
	25% case fatality	40% case fatality	Very low	Low	Moderate	High	Very high
			Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.10	0.16	0.01	0.03	0.08	0.33[b]	0.65[b]
30 to 39	0.10	0.16	0.01	0.06	0.15[a]	0.59[b]	1.18[b]
40 to 49	0.10	0.16	0.02	0.10[a]	0.25[b]	1.00[b]	2.00[b]
50 to 59	0.10	0.16	0.05	0.23[b]	0.57[b]	2.26[b]	4.52[b]
60 to 69	0.10	0.16	0.05	0.25[b]	0.62[b]	2.47[b]	4.95[b]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT only for the lower case fatality estimate

[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT for both case fatality estimates

Table 34. Expected VITT deaths by age group (based on VITT rate of 1 per 100,000) compared to expected deaths due to COVID-19 prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios

Age Group	Expected deaths due to VITT per 100,000		Scenario activity level (daily incidence of reported COVID-19 cases)				
	25% case fatality	40% case fatality	Very low	Low	Moderate	High	Very high
			Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.25	0.40	0.01	0.03	0.08	0.33[b]	0.65[b]
30 to 39	0.25	0.40	0.01	0.06	0.15	0.59[b]	1.18[b]
40 to 49	0.25	0.40	0.02	0.10	0.25[a]	1.00[b]	2.00[b]
50 to 59	0.25	0.40	0.05	0.23	0.57[b]	2.26[b]	4.52[b]

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60 to 69	0.25	0.40	0.05	0.25[a]	0.62[b]	2.47[b]	4.95[b]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT only for the lower case fatality estimate

[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT for both case fatality estimates

Benefit-risk analysis for the Janssen COVID-19 vaccine

Table 35. Expected VITT cases by age group (based on VITT incidence rate of 1 per 500,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.20	0.03	0.15	0.38[a]	1.51[a]	3.03[a]
30 to 39	0.20	0.04	0.22[a]	0.55[a]	2.19[a]	4.38[a]
40 to 49	0.20	0.04	0.22[a]	0.54[a]	2.16[a]	4.32[a]
50 to 59	0.20	0.04	0.20[b]	0.50[a]	2.00[a]	4.01[a]
60 to 69	0.20	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

[b] Potentially prevented ICU admissions due to COVID-19 is equivalent to expected ICU admissions due to VITT

Table 36. Expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.03	0.15	0.38	1.51[a]	3.03[a]
30 to 39	0.40	0.04	0.22	0.55[a]	2.19[a]	4.38[a]
40 to 49	0.40	0.04	0.22	0.54[a]	2.16[a]	4.32[a]
50 to 59	0.40	0.04	0.20	0.50[a]	2.00[a]	4.01[a]
60 to 69	0.40	-	-	-	-	-

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N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.
[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 37. Expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.03	0.15	0.38	1.51[a]	3.03[a]
30 to 39	1.00	0.04	0.22	0.55	2.19[a]	4.38[a]
40 to 49	1.00	0.04	0.22	0.54	2.16[a]	4.32[a]
50 to 59	1.00	0.04	0.20	0.50	2.00[a]	4.01[a]
60 to 69	1.00	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.
[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 38. Expected VITT deaths by age group (based on VITT rate of 1 per 500,000) compared to expected deaths due to COVID-19 prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected deaths due to VITT per 100,000 20% case fatality	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.04	0.00	0.02	0.06[b]	0.23[b]	0.47[b]
30 to 39	0.04	0.01	0.04[a]	0.10[b]	0.39[b]	0.78[b]
40 to 49	0.04	0.01	0.05[b]	0.12[b]	0.50[b]	1.00[b]
50 to 59	0.04	0.02	0.08[b]	0.19[b]	0.75[b]	1.51[b]
60 to 69	0.04	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.
[a] Potentially prevented deaths due to COVID-19 is equivalent to the expected deaths due to VITT
[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT

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Table 39. Expected VITT deaths by age group (based on VITT rate of 1 per 250,000) compared to expected deaths due to COVID-19 prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected deaths due to VITT per 100,000 20% case fatality	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.08	0.00	0.02	0.06	0.23[b]	0.47[b]
30 to 39	0.08	0.01	0.04	0.10[b]	0.39[b]	0.78[b]
40 to 49	0.08	0.01	0.05	0.12[b]	0.50[b]	1.00[b]
50 to 59	0.08	0.02	0.08[a]	0.19[b]	0.75[b]	1.51[b]
60 to 69	0.08	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 is equivalent to the expected deaths due to VITT

[b] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT

Table 40. Expected VITT deaths by age group (based on VITT rate of 1 per 100,000) compared to expected deaths due to COVID-19 prevented by early Janssen vaccination under five different COVID-19 activity scenarios

Age Group	Expected deaths due to VITT per 100,000 20% case fatality	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented deaths due to COVID-19 per 100,000				
20 to 29	0.20	0.00	0.02	0.06	0.23[a]	0.47[a]
30 to 39	0.20	0.01	0.04	0.10	0.39[a]	0.78[a]
40 to 49	0.20	0.01	0.05	0.12	0.50[a]	1.00[a]
50 to 59	0.20	0.02	0.08	0.19	0.75[a]	1.51[a]
60 to 69	0.20	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented deaths due to COVID-19 exceeds expected deaths due to VITT

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There is uncertainty in the base case risk analysis for ICU admissions due to incomplete reporting in the surveillance data at the national level, with ICU admission status known for only one-third of cases. We therefore conducted sensitivity analyses to examine scenarios representing ICU admissions that may reflect more recent trends, including the increasing proportion of VOC cases, and account for underreporting and right-censoring in surveillance data. We defined this scenario by estimating the proportion of ICU admissions by age group over the period February 1, 2021 to April 12, 2021 in a representative province and applying those proportions to the recent average overall ICU admission rate (approximately 0.43 per 100,000). We then apply the same scenarios for activity levels and assumptions for wait times for mRNA vaccines and vaccine effectiveness from our base case. We also applied this analysis to a range of daily rates of ICU admissions (per 100,000) .

Table 41. Proportion of total ICU admissions by age group based on representative provincial data

Age Group	Proportion of total ICU admissions
20 to 29	2.17%
30 to 39	4.56%
40 to 49	8.18%
50 to 59	20.59%
60 to 69	24.78%

Sensitivity analysis for the AstraZeneca COVID-19 vaccine

Table 42. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios using a high ICU admission rate (0.43 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.05	0.26	0.64[a]	2.55[a]	5.10[a]
30 to 39	0.40	0.10	0.48[a]	1.21[a]	4.84[a]	9.68[a]
40 to 49	0.40	0.12	0.62[a]	1.54[a]	6.18[a]	12.35[a]
50 to 59	0.40	0.21	1.05[a]	2.62[a]	10.48[a]	20.96[a]
60 to 69	0.40	0.10	0.50[a]	1.26[a]	5.05[a]	10.09[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

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Table 43. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios using a high ICU admission rate (0.43 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.05	0.26	0.64	2.55[a]	5.10[a]
30 to 39	1.00	0.10	0.48	1.21[a]	4.84[a]	9.68[a]
40 to 49	1.00	0.12	0.62	1.54[a]	6.18[a]	12.35[a]
50 to 59	1.00	0.21	1.05[a]	2.62[a]	10.48[a]	20.96[a]
60 to 69	1.00	0.10	0.50	1.26[a]	5.05[a]	10.09[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 44. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios using a lower ICU admission rate (0.22 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.03	0.13	0.32	1.28[a]	2.55[a]
30 to 39	0.40	0.05	0.24	0.60[a]	2.42[a]	4.84[a]
40 to 49	0.40	0.06	0.31	0.77[a]	3.09[a]	6.18[a]
50 to 59	0.40	0.10	0.52[a]	1.31[a]	5.24[a]	10.48[a]
60 to 69	0.40	0.05	0.25	0.63[a]	2.52[a]	5.05[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 45. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early AstraZeneca vaccination under five different COVID-19 activity scenarios using a lower ICU admission rate (0.22 per 100,000)

Age Group		Scenario activity level (daily incidence of reported COVID-19 cases)

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	Expected ICU admissions due to VITT per 100,000	Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.03	0.13	0.32	1.28[a]	2.55[a]
30 to 39	1.00	0.05	0.24	0.60	2.42[a]	4.84[a]
40 to 49	1.00	0.06	0.31	0.77	3.09[a]	6.18[a]
50 to 59	1.00	0.10	0.52	1.31[a]	5.24[a]	10.48[a]
60 to 69	1.00	0.05	0.25	0.63	2.52[a]	5.05[a]

N.B. Unless noted, the potential event of interest prevented by earlier AstraZeneca vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Sensitivity analysis for the Janssen COVID-19 vaccine

Table 46. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 500,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios using a high ICU admission rate (0.43 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.20	0.04	0.18	0.45[a]	1.82[a]	3.64[a]
30 to 39	0.20	0.06	0.32[a]	0.81[a]	3.23[a]	6.46[a]
40 to 49	0.20	0.06	0.31[a]	0.77[a]	3.08[a]	6.16[a]
50 to 59	0.20	0.07	0.35[a]	0.87[a]	3.49[a]	6.99[a]
60 to 69	0.20	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 47. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios using a high ICU admission rate (0.43 per 100,000)

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Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.04	0.18	0.45[a]	1.82[a]	3.64[a]
30 to 39	0.40	0.06	0.32	0.81[a]	3.23[a]	6.46[a]
40 to 49	0.40	0.06	0.31	0.77[a]	3.08[a]	6.16[a]
50 to 59	0.40	0.07	0.35	0.87[a]	3.49[a]	6.99[a]
60 to 69	0.40	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 48. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early Jassen vaccination under five different COVID-19 activity scenarios using a high ICU admission rate (0.43 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.04	0.18	0.45	1.82[a]	3.64[a]
30 to 39	1.00	0.06	0.32	0.81	3.23[a]	6.46[a]
40 to 49	1.00	0.06	0.31	0.77	3.08[a]	6.16[a]
50 to 59	1.00	0.07	0.35	0.87	3.49[a]	6.99[a]
60 to 69	1.00	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 49. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 250,000) compared to expected COVID-19 ICU admissions prevented by early Janssen vaccination under five different COVID-19 activity scenarios using a lower ICU admission rate (0.22 per 100,000)

Age Group	Expected ICU admissions due	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high

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	to VITT per 100,000	Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	0.40	0.02	0.09	0.23	0.91[b]	1.82[b]
30 to 39	0.40	0.03	0.16	0.40[a]	1.61[b]	3.23[b]
40 to 49	0.40	0.03	0.15	0.39	1.54[b]	3.08[b]
50 to 59	0.40	0.03	0.17	0.44[b]	1.75[b]	3.49[b]
60 to 69	0.40	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 is equivalent to expected ICU admissions due to VITT

[b] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Table 50. Sensitivity analysis of expected VITT cases by age group (based on VITT incidence rate of 1 per 100,000) compared to expected COVID-19 ICU admissions prevented by early Jassen vaccination under five different COVID-19 activity scenarios using a lower ICU admission rate (0.22 per 100,000)

Age Group	Expected ICU admissions due to VITT per 100,000	Scenario activity level (daily incidence of reported COVID-19 cases)				
		Very low	Low	Moderate	High	Very high
		Potentially prevented ICU admissions due to COVID-19 per 100,000				
20 to 29	1.00	0.02	0.09	0.23	0.91	1.82[a]
30 to 39	1.00	0.03	0.16	0.40	1.61[a]	3.23[a]
40 to 49	1.00	0.03	0.15	0.39	1.54[a]	3.08[a]
50 to 59	1.00	0.03	0.17	0.44	1.75[a]	3.49[a]
60 to 69	1.00	-	-	-	-	-

N.B. Unless noted, the potential event of interest prevented by earlier Janssen vaccination compared to waiting for mRNA vaccine is lower than the event of interest due to VITT.

[a] Potentially prevented ICU admissions due to COVID-19 exceeds expected ICU admissions due to VITT

Limitations of analysis

There are some limitations to this analysis to consider when interpreting the benefit-risk estimates.

1) Each scenario is based on a constant incidence rate and assumes an unvaccinated population. However, the risk of COVID-19 is dynamic and difficult to predict. As a result, the estimated benefits of preventing COVID-19 outcomes with each viral vector

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vaccine compared to waiting for an mRNA vaccine will be more uncertain for age groups with longer wait times for mRNA vaccines.

2) The risk of ICU admission and death was based on the age distribution of cases in surveillance data where unreported cases are not uniformly distributed across age groups. Moreover, ICU admission status in the data used for the base case analysis was only known for approximately 33% of reported cases as of April 14, 2021. Thus, there is uncertainty in the relative benefits between age groups in preventing ICU admissions with using one of the viral vector vaccines compared to waiting for an mRNA vaccine.
3) The rate of ICU admissions relative to daily reported cases may vary considerably across provinces and territories due to different epidemiology (e.g. variants of concern), demographics (e.g. age and comorbidity profile in the population), testing policies, hospital capacity and vaccination rollout strategies. The benefit-risk of each viral vector vaccine should be interpreted with caution in the scenarios provided.
4) This analysis did not account for ICU capacity limits. In scenarios where incidence rates result in overflow of ICU capacity this analysis will underestimate the benefits of preventing deaths with vaccination using each viral vector vaccine. However, if such a scenario is considered likely, then the benefit-risk estimates from the high or very high scenario may be most applicable.
5) Estimates of VITT incidence and mortality are still highly uncertain and may change as evidence continues to emerge.
6) Time to wait to receive an mRNA vaccine assumes an age-based rollout and vaccine administration to be 100% efficient (i.e., weekly supply is consumed by the end of the week). If vaccine uptake is delayed or slower than anticipated, the cumulative risks of COVID-19 outcomes will increase, particularly in age groups facing longer wait times for mRNA vaccines.
7) Administration of each viral vector vaccine, as described in these scenarios, is assumed to take place in mid-April 2021. Any delay in administering the vaccine to a particular age group shortens the time period to wait for mRNA and therefore reduces the benefit of early administration with viral vector vaccines.

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APPENDIX G: PREGNANCY, BREASTFEEDING, AND COVID-19 VACCINE REGISTRIES

There is a Canadian COVID-19 vaccine registry for pregnant and breastfeeding individuals:

- Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals

Table 51: Pregnancy registry information by vaccine product

Vaccine product	Registry information
Pfizer-BioNTech COVID-19 vaccine	Pfizer does not have a pregnancy exposure registry. Pfizer COVID-19 vaccine recipients and health care providers are encouraged to report any exposure to COVID-19 vaccine during pregnancy or breastfeeding to the vaccine manufacturer (1-866-723-7111).
Moderna COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the Moderna COVID-19 vaccine during pregnancy. Women who are vaccinated with the Moderna COVID-19 vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866- 663- 3762).
AstraZeneca COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AstraZeneca COVID-19 vaccine during pregnancy. Women who are vaccinated with AstraZeneca COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com or calling 1-800-616-3791.
Janssen COVID-19 vaccine	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 vaccine during pregnancy. Women who are vaccinated with Janssen COVID-19 vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com

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From: Stewart, Iain (PHAC/ASPC)

Sent: 2020-12-07 8:37 AM

To: Elmslie, Kim (PHAC/ASPC); Tam, Dr Theresa (PHAC/ASPC)

Cc: Njoo, Howard (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC)

Subject: RE: [redacted]

[redacted]

-----Original Message-----
From: Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Sent: 2020-12-07 8:10 AM
To: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>
Cc: Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; Rendall, Jennifer (PHAC/ASPC) <jennifer.rendall@canada.ca>
Subject: [redacted]

[redacted]

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National Advisory Committee on Immunization (NACI)

Summary of Updated NACI COVID-19 Vaccine Statement of May 3, 2021

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Canada

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1 | SUMMARY OF UPDATED NACI VACCINE STATEMENT OF APRIL 20, 2021

Overview

- COVID-19 vaccination is essential to ending the pandemic. NACI encourages all Canadians to get vaccinated with a complete series of COVID-19 vaccine to protect themselves, their families, and their communities from illness, hospitalizations and deaths from COVID-19.

- NACI has updated its Recommendations on the use of COVID-19 vaccines to include advice on the use of the Janssen COVID-19 vaccine. NACI has also reaffirmed its recommendation on COVID-19 vaccination during pregnancy.

- The Janssen COVID-19 vaccine is a single dose, viral vector vaccine authorized for use in Canada for adults 18 years of age and over. Health Canada has determined that it is a safe and effective vaccine.

- NACI assesses how best to use an authorized vaccine to achieve the greatest public health benefits. It analyzes the spread of COVID-19 in Canada and the risks for population subgroups; it applies data on the safety and effectiveness of COVID-19 vaccines from studies of their real-world use and develops advice on the equitable use of vaccines in immunization programs given vaccine supplies.

- At this time and based on current evidence, NACI recommends the Janssen COVID-19 vaccine may be offered to individuals 30 years of age and older without contraindications, if the individual does not wish to wait for an mRNA vaccine and if the benefits outweigh the risk for the individual.

- NACI recognizes that public health benefit-risk analyses for the use of the Janssen vaccine may vary between jurisdictions based on their unique circumstances, including local COVID-19 epidemiology; local vaccine supply and logistics; and equity considerations. These factors change over time.

- As a single dose vaccine, the Janssen vaccine may be better suited for populations that are harder to schedule for a second dose (e.g., mobile populations and certain hard to reach populations).

- NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide and the absence of safety signals of concern. NACI notes that Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

- NACI recommends that a complete vaccine series, preferably with an mRNA COVID-19 vaccine, may be offered during pregnancy, if the benefits outweigh the risks for the individual and the fetus. An mRNA vaccine is preferred due to recently published data indicating the safety of mRNA vaccines during pregnancy, and concerns about the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) during pregnancy, should it occur following the administration of a viral vector vaccine.

- NACI also reaffirms that, until further evidence emerges, those previously infected with SARS-CoV-2 be offered a complete series with a COVID-19 vaccine.

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- Public health measures remain the foundation of the pandemic response while vaccines continue to roll out across the country. It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.
- To see the full update, please visit Recommendations on the use of COVID-19 vaccines.

Background

Main Recommendation

- NACI has updated its Recommendations on the use of COVID-19 vaccines to include advice on the Janssen COVID-19 vaccine, a viral vector vaccine.
- Health Canada authorized the Janssen COVID-19 viral vector vaccine for individuals 18 years of age and older on March 5, 2021. It is a single dose vaccine that can be kept at refrigerated temperatures.
- NACI assesses how best to use authorized vaccines to achieve the greatest public health benefits. It analyzes the spread of COVID-19 in Canada and the risks for population subgroups; it applies data on the safety and effectiveness of COVID-19 vaccines from studies of their real-world use and develops advice on the equitable use of vaccines in immunization programs given vaccine supplies.
- NACI met on March 16, 25 and April 13, 26, 2021, to review the most up to date clinical trial data and effectiveness evidence from the real-world use of the Janssen vaccine. NACI also considered Canada's rapidly changing COVID-19 epidemiology; Canada's COVID-19 vaccine supply, including the specific qualities that make a particular vaccine best suited for certain populations or age-groups; and principles of ethical decision-making. NACI continues to review evidence as it evolves.
- Clinical trial data available to date demonstrate the single dose Janssen vaccine is 67% efficacious against moderate to severe symptomatic COVID-19 infection across all age groups, at least two weeks after receiving the vaccine. The vaccine was also highly efficacious in preventing critical illness and hospitalization.
- In addition, preliminary evidence suggests the Janssen vaccine offers protection against the B.1.351 variant of concern first identified in South Africa, and the P.2 variant of interest first identified in Brazil. There is no data on the P.1 variant of concern first identified in Brazil.
- There have been confirmed reports of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) after administration of the Janssen viral vector vaccine, as seen with the AstraZeneca viral vector vaccine. NACI weighed the benefits of the Janssen vaccine in saving lives and protecting populations against serious complications of COVID-19 against the risk of developing VITT.
- At this time and based on current evidence, NACI recommends a complete series with viral vector COVID-19 vaccine (AstraZeneca, Janssen) may be offered to individuals 30 years of

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age and older without contraindications if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine and if the following conditions apply:
    - A benefit-risk analysis determines that the benefit of earlier vaccination with the viral vector COVID-19 vaccine outweighs the risk of the individual getting COVID-19 while waiting for an mRNA COVID-19 vaccine;
    - The individual provides informed consent once the benefits and risks of VITT compared to COVID-19 are clearly outlined, including how long the individual will have to wait for an mRNA vaccine and public health measures the individual is able to take to minimize their exposure to the COVID-19 virus; and
    - The individual will have to wait in order to receive an mRNA vaccine.

- This recommendation provides provinces and territories with guidance on how to optimize the use of the Janssen vaccine in their jurisdictions to achieve the greatest public health benefit.

- The public health benefit-risk analysis for the use of the vaccine may vary between jurisdictions. Provinces and territories adapt NACI's recommended age threshold based on their unique circumstances, including local COVID-19 epidemiology, local vaccine supply and logistics and equity considerations. Health officials can refer to a Risk Assessment Tool for the use of the Janssen vaccine included in NACI's updated statement.

- Healthcare professionals should be aware of VITT, including how to diagnose and treat the condition. Individuals who receive the Janssen vaccine should monitor their health and immediately seek medical attention if they develop symptoms of VITT.

- NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide and the absence of any safety signals of concern. NACI notes that Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the eligible Canadian population before fall 2021.

Recommendation on COVID-19 Vaccination During Pregnancy

- NACI recommends that a complete vaccine series with a COVID-19 vaccine (preferably with an mRNA vaccine) may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the evidence of the use of COVID-19 vaccines in this population.

- mRNA vaccines (Pfizer-BioNTech, Moderna) are preferred for use in pregnant individuals due to recently published data from a study in the United States indicating the mRNA COVID-19 vaccines are safe in pregnant women. In addition, treating VITT in pregnant individuals, should it occur following the administration of a viral vector vaccine, is complex. Based on current evidence, VITT does not seem to be associated with the use of mRNA vaccines.

Recommendation on COVID-19 Vaccination for People Previously Infected with SARS-CoV-2 Virus

- NACI continues to recommend that people previously infected with the SARS-CoV-2 virus be offered a complete series of a COVID-19 vaccine.

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- In the absence of one-dose vaccine effectiveness data in people who were previously infected and limited second-dose safety data, people with previous SARS-CoV-2 infection should continue to receive a complete vaccine series, regardless of the severity of their previous infection.

- NACI will continue to closely monitor the evolving data on COVID-19 vaccines and will update its recommendations as needed.

To see the full update, please visit Recommendations on the use of COVID-19 vaccines.

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From: Stewart, Iain (PHAC/ASPC)
Sent: 2020-11-16 9:47 PM
To: Romano, Anna (PHAC/ASPC)
Cc: Denis, Joel (PHAC/ASPC)
Subject: RE: We don't have vaccine injury compensation EFU or B2021 ask?

I had forgotten [redacted]

From: Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>
Sent: 2020-11-16 5:53 PM
To: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
Cc: Denis, Joel (PHAC/ASPC) <joel.denis@canada.ca>
Subject: FW: We don't have vaccine injury compensation EFU or B2021 ask?

Apologies for the delay in getting back to you. See answer below.

-----Original Message-----
From: Denis, Joel (PHAC/ASPC) <joel.denis@canada.ca>
Sent: 2020-11-16 5:49 PM
To: Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>
Cc: Anderson3, Jennifer (PHAC/ASPC) <jennifer.anderson3@canada.ca>
Subject: RE: We don't have vaccine injury compensation EFU or B2021 ask?

[redacted]

-----Original Message-----
From: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
Sent: 2020-11-16 4:37 PM
To: Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>
Subject: Re: We don't have vaccine injury compensation EFU or B2021 ask?

[redacted]

Sent from my iPhone

> On Nov 16, 2020, at 4:09 PM, Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca> wrote:
>

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[redacted]

>
> -----Original Message-----
> From: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
> Sent: 2020-11-16 3:35 PM
> To: Romano, Anna (PHAC/ASPC) <anna.romano@canada.ca>
> Subject: We don't have vaccine injury compensation EFU or B2021 ask?
>
>
>
> Sent from my iPhone

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From: King2, Arlene (PHAC/ASPC)

Sent: 2020-11-22 1:52 PM

To: Tam, Dr Theresa (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC)

Subject: Re: Vaccine safety

Attachments: FINAL Vaccine Safety Plan for VTF September 16 2020.docx; Pennock October 22.pptx

---

FYI

-----Original Message-----
From: Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca>
Sent: 2020-11-22 10:01 AM
To: King2, Arlene (PHAC/ASPC) <arlene.king2@canada.ca>; Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Subject: I am going to be late

Have another call will join as soon as I can

Sent from my iPhone

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Post-market surveillance of COVID-19 vaccine safety – September 15, 2020

Objective: To rapidly detect vaccine safety signals that may require regulatory action.

Component	Description	Timeliness	Planned Innovation for COVID-19 Vaccine Deployment	Timeline
Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)	-All provinces and territories (PTs) report adverse events following immunizations (AEFIs) to PHAC. AEFI reporting is mandated under public health legislation in all jurisdictions except for Yukon and Newfoundland. -AEFI reports from PTs are collated into CAEFISS on a weekly basis. -Reports include information on demographics and underlying health conditions.	-Deaths are reported to PHAC within 24 hours. -Serious AEFIs are reported to PHAC within 15 days. This delay is necessary to collect information on underlying conditions, outcomes, medical treatment sought, and other diagnosis that may explain the event.	-Expedited reporting for AEFIs of interest as identified through Phase III trials (ie, expand the list of AEFIs to be reported to PHAC within 24 hours). -Weekly reporting of all COVID-19 AEFIs to PHAC. -Enhanced AEFI reporting by PTs including ethnicity, and priority populations (health care workers, long-term care residents). -Refine the existing signal response protocol and test it with the regulator. -Increase number of PTs that upload their data directly into CAEFISS (currently: BC, AB and QC. In the works: ON). -Explore other IT solutions to enhance timeliness of reporting.	Pending completion of Phase III trials In place Discussions underway December 2020 December 2020 Discussions underway
Canada Vigilance (Health Canada)	-AEFIs reported to Health Canada by Market Authorization Holders and members of the general public	-System is updated monthly	-Expedited timeliness and completeness of reporting.	Discussions pending
Causality Assessment	-All AEFIs are currently reviewed by Medical Officers of Health at the local, PT and Federal level	As needed when a signal is identified.	-Establish the Expert Advisory Committee on Causality Assessment to determine the role of the COVID-19 vaccine in serious AEFIs. -Rapid development of a safety profile of COVID-19 vaccine(s), including available international data.	November 2020
Active AEFI surveillance	-IMPACT network of 12 pediatric hospitals actively searches for AEFIs among hospital admissions -Canadian National Vaccine Safety Network (CANVAS) under the Canadian Immunization Research Network (CIRN) assesses vaccine safety at sentinel sites during immunization campaigns.	-Weekly reporting to PHAC -Weekly reporting to PHAC	-Increase expedited reporting for these networks according to AEFIs of interest as identified through Phase III trials (ie, expand the list of AEFIs to be reported to PHAC within 24 hours). -Activate the CANVAS network for the COVID-19 immunization campaign with increased funding to CIRN.	Discussions pending November 2020
CAEFISS Dissemination	-Vaccine Safety reports are published on the PHAC website.	-Twice per year	-Interactive dashboard published on PHAC website summarizing AEFI data and enabling users to break down data by demographic factors and vaccines. -Move to weekly on-line updates on the PHAC website.	December 2020 December 2020

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Canada

Vaccine safety, coverage and effectiveness

October 22, 2020

PROTECTING AND EMPOWERING CANADIANS
TO IMPROVE THEIR HEALTH

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The 'basic' questions PHAC will need to answer….

- How many people have been vaccinated?
- How do we know that the vaccine(s) is/are safe?
- How do we know that the vaccine(s) is/are effective in the 'real world'?

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Beyond the Basics…

- **How many people have been vaccinated?**
  - What about sub-populations (e.g. HCWs, Residents in LTCF, Indigenous)?
  - Who is *not* being vaccinated?
  - Are there equity gaps?

- **How do we know that the vaccine(s) is/are safe?**
  - What process kicks in if a safety signal is observed?
  - Will concerns about safety affect Canadians' willingness to get the vaccine?
  - How do we know that the vaccine caused the observed safety signals?
  - What's going on internationally?

- **How do we now that the vaccine(s) is/are effective in the 'real world'?**
  - What if it's not found to be 'effective'?

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Vaccine Coverage

- Vaccine coverage measures the proportion of the population that has received a vaccine
  - Data on coverage is usually collected and monitored through electronic immunization registries which are in place in most provinces and territories
  - PHAC assesses vaccine coverage through immunization coverage surveys which provides more detailed information on factors associated with vaccination (risk groups, unvaccinated)

- PHAC has already been working with PTs and Statistics Canada to enhance current systems in anticipation of the COVID-19 vaccine campaign:
  - PTs have agreed to share weekly coverage counts with PHAC
  - PHAC is investing in existing registries to make necessary enhancements
  - Statistics Canada will be conducting regular surveys during the vaccination campaign to provide National-level coverage estimates along with information on unvaccinated.

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Vaccine Coverage: Risks

- Demands for 'real-time' information will outstrip current system capacity at the PT level to report coverage more frequently
  - PTs have signalled the need for additional resources to provide data more frequently
- Information on sub-populations (such as Indigenous identity, ethnicity, HCW, residents of LTCF) will be difficult to impossible for PTs to collect
- PTs cite privacy as a reason for putting limits on how coverage data can be shared and used by the Public Health Agency of Canada
- The 'black box' – between inventory (doses) and coverage (people)
  - 'Multiple provider' models in place in many PTs make immunizations difficult to track
  - Tracking a two-dose regimen will add a layer of complexity

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Vaccine Coverage: Where we want to be and who we need to work with

- 'Interoperability' between PT registries so that PHAC can get data directly from provinces and territories
  - Enhancing use of current systems, not developing a new one

- Additional functionality to registries in order to:
  - Link inventory with coverage
  - Track special populations

- Incentivize bar code technology to modernize immunization tracking writ large

Working closely with other V-RAT streams:

- Communications and Public Engagement
- National Vaccine Tracking and Platform
- Vaccine Logistics

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Vaccine Safety

Reporting on adverse events following immunization (AEFIs)

- Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

Canada has a robust vaccine safety program in place that is a joint undertaking between:

- Industry (Market Authorization Holders)
- Health Canada (the Regulator)
- PHAC (as a promoter and funder of vaccinations)
- Provincial and Territorial (PT) public health authorities (who deliver immunization programs)

There is an established process within HC, PHAC and the PTs to rapidly convene to discuss and act on potential safety signals.

PHAC is building on vaccine safety methods used during H1N1 vaccine deployment to prepare for the COVID-19 vaccine deployment.

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Vaccine Safety Activities underway in anticipation of COVID-19 vaccine deployment

Input into I/O Ts &Cs for expedited review

- Sets requirements for vaccine safety information from manufacturers

Refined signal response protocol

- Updating and testing the signal response protocol that defines roles and responsibilities in the event a safety signal is detected

Weekly AEFI reporting to PHAC

- All PTs agree to expedited AEFI reporting during COVID-19 vaccination campaign

Causality assessment

- Establish an expert group in support of a Vaccine Injury Compensation Program

Improved knowledge translation and reporting

- Development of a 'one stop shop' for national-level influenza vaccine AEFIs

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Vaccine Safety: Risks

- Demands for 'real-time' information will outstrip current system capacity at the PT level to AEFIs more frequently
  - PTs have signalled the need for additional resources to provide safety information more frequently

- We need safety data from Phase III Clinical Trials to make adjustments to our current systems

- Access to medical information to facilitate causality assessment

- PHAC is currently not sharing vaccine safety data internationally, due to privacy concerns raised by PTs

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Vaccine Safety: Where we want to be and who we need to work with

- Safety system that quickly identifies and responds to safety signals and intervenes when necessary
  - Transparency and timeliness in reporting
  - Assurances to Canadians that we are actively monitoring for safety signals
  - Provide 'back up' to Canadians for getting vaccinated (VIC)

- Active contributor on the international stage.

Working closely with other V-RAT streams:

- Policy and Coordination (VIC)
- Vaccine Selection
- Communications and Public Engagement
- National Vaccine Tracking and Platform
- Immunization Readiness

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Vaccine Effectiveness (VE): A research endeavour

- VE measures the effectiveness of the vaccine in 'real world' settings

- Two existing research networks can be mobilized to provide such measurements:
  - Hospital-based to assess effectiveness against hospitalizations
  - Community-based to assess effectiveness against primary care visits

- Rapidly expanding research area which requires some federal leadership

- Investments in networks, capacity building

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Key Items for Resolution

- A higher level conversation with PTs about privacy and information as it pertains to information sharing during vaccine deployment
  - Privacy issues are not insurmountable, and can be managed
  - Risk for privacy breach is low

- Investments in PT reporting systems should be coordinated with other V-RAT work stream investments
  - Expectations for information sharing should be attached

- How to best utilize existing systems to enhance reporting systems

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Back pocket, more detailed slides

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Capture of COVID-19 vaccinations in provincial and territorial immunization registries

Notes: PT representatives on the Canadian Immunization Registries and Coverage (CIRC) Network were asked whether, if COVID-19 mass vaccination is initiated in 2021, their registry could capture all these vaccinations

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VACCINE SAFETY IN CANADA

1 DEVELOPMENT

- Disease targeted for a vaccine. Research and development takes place.
- Pre-clinical tests in laboratory: *Can it work? Is it safe?*
- Researchers and manufacturer conduct clinical trials:

PHASE
1. **Several volunteers:** *Is it safe?*
2. **Hundreds of volunteers:** *Is it safe? What's the ideal dose?*
3. **Thousands of volunteers:** *Is it safe? How well does it work?*

- Ethical review is done on all vaccine research to ensure it meets the highest ethical standards and that the greatest protection is provided to participants who serve as research subjects.

2 TESTING & APPROVAL

- Health Canada examines results of clinical trials:
  - Is the vaccine safe?
  - Does it work?
  - Which age groups?
  - How many doses?
  - Interval between doses?
  - Side effects?
  - Are the samples of consistent quality?
  - Do the manufacturing facilities meet quality control standards?
- Health Canada approves the vaccine if it is determined to be safe, protective, and of high quality.

3 RECOMMENDATIONS

- National Advisory Committee on Immunization* (NACI) reviews evidence on the best use of the vaccine:

REVIEW
- Who would benefit most from the vaccine?
- How does it compare to similar vaccines?
- Are there additional and ongoing safety data available?
- How are other countries using it?
- What additional research questions need to be addressed?

- Following Public Health Agency of Canada (PHAC) approval, the recommendations are made available to healthcare providers.
- Each province/territory decides on vaccine's use:
  - Should it be publicly-funded (free)? If so, for whom?
  - Where will it be available - Schools? Pharmacies? Doctors' offices? Public Health Clinics?

*The National Advisory Committee on Immunization (**NACI**) has been recognized for **over 60 years** and is comprised of experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health.

4 MANUFACTURING, TRANSPORT & STORAGE

- Manufacturer tests each batch of the vaccine to ensure pre-set quality standards are met.
- Health Canada inspects the manufacturing facilities and reviews vaccine lots before they are sold in Canada to ensure consistency and quality.
- Packaged and labelled vaccines are carefully stored and transported from manufacturer, to destination site and final administration, under controlled temperature ("cold chain").

5 VACCINATION

- A licensed health professional administers the vaccine and records details for the patient's record.
- Provincial, territorial and federal officials meet regularly to discuss vaccines and immunization programs:
  - Have there been any safety issues?
  - Has it reduced this disease in Canada?
  - Are there new recommendations or products available?
  - Do we have enough supply to meet the needs of Canadians?

6 MONITORING

- For as long as a vaccine is used in Canada, it is monitored for adverse events following immunization (AEFI).
- AEFIs are reported by:
  - The general public
  - Health professionals
  - A network of pediatric hospitals
  - Local public health units
  - Provincial surveillance systems
  - Networks of vaccine researchers conducting studies
  - International monitoring
  - Manufacturers
- PHAC and Health Canada review all AEFIs and investigate safety concerns. Actions are taken as required.
- NACI* updates its recommendations to incorporate new information as it becomes available.

Note: Together, all of these steps can take more than **10 years** to complete. Once available to Canadians, each vaccine is constantly monitored for safety and quality for as long as it is used.

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Canada.ca/vaccines

Canada

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Established process to rapidly convene to discuss potential safety signals

Long-established expedited timelines for PT reporting of adverse events considered high priority (e.g., death, serious and unexpected events)

- **Death:** PHAC notified within 24 hours of awareness by the PT. Details submitted as they become available
- **Other serious and unexpected events:** Aggregate counts submitted to PHAC weekly. Complete reports submitted within 15 days

When vaccine safety signal detected:

- Daily calls (or as needed) between relevant PTs, HC, PHAC and the vaccine manufacturer
- Consultation with WHO, as required
- Further investigation, causality assessment and required actions, as required

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Vaccine safety activities: AEFI Signal Response Protocol

Definition

- Signal response = set of activities performed to determine whether there are new risks associated with a vaccine product or whether known risks have changed.

Main goals

- Enhance collaboration and coordination among partners
- Provide guidelines in detection of and response to vaccine safety signals
- Improve efficiency and effectiveness of response

Current status

- Revised draft in final stages

Next steps

- Submission to VVWG for review and to CIC for endorsement in Fall 2020

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Vaccine safety activities: expedited AEFI reporting

Current status

- Established process for expedited reporting during annual influenza vaccination campaigns
- VVWG agreement to follow same process during COVID-19 vaccination campaign
- Expedited AEFI reporting SOP developed jointly with VVWG

Next steps

- New electronic reporting system using CNPHI
  - Secure online data collection platform
  - PTs can directly enter and upload AEFI counts
  - Can easily revise reporting template
- New system will be in place for COVID-19 vaccination
- Finalization of SOP with VVWG in Fall 2020

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Vaccine safety activities: active surveillance

Definition

- Active epidemiologic surveillance = proactively searching for/requesting information to collect disease information

Current status

- VVWG agreement in principle to develop PT-based active surveillance system for COVID-19 vaccine AEFIs in those target groups vaccinated first (e.g., HCW, LTCF residents)
- Creation of task group to develop proposal
  - PHAC and HC
  - PTs
  - External experts – CANVAS and IMPACT

Next steps

- Submission of proposed options to VVWG in Fall 2020

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Vaccine safety activities: reporting products

Current status

- Bi-annual and annual reports
- Development of interactive dashboard for national-level influenza vaccine AEFIs
  - VVWG endorsement received in March 2020

Next steps

- Collaborate with PHAC's Infobase Team to post influenza vaccine AEFI dashboard on-line
- Expand dashboard for reporting COVID-19 vaccine AEFIs
- Development of weekly epi summary of COVID-19 vaccine safety data
- Expand dashboard for reporting all AEFIs

ATIA-16(2)(c)

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From: Tam, Dr Theresa (PHAC/ASPC)
Sent: 2020-12-09 10:15 AM
To: Robinson, Kerry (PHAC/ASPC); Stewart, Iain (PHAC/ASPC)
Subject: Re: Annotated Agenda Joint CDMH - Intergovernmental DMs Meeting Today @ 10:30 am

---

Suggest we don't use the term VISP in capitals as we have not landed on a name for the vaccine injury compensation scheme.

Sent from my iPad

On Dec 9, 2020, at 10:08 AM, Robinson, Kerry (PHAC/ASPC) wrote:

Attached is the latest federal annotated agenda from HC. Regulatory section was updated.
Kerry

From: Robinson, Kerry (PHAC/ASPC)
Sent: 2020-12-09 8:45 AM
To: Stewart, Iain (PHAC/ASPC) ; Tam, Dr Theresa (PHAC/ASPC)
Cc: 'Romano, Anna (PHAC/ASPC)' ; Evans, Cindy (PHAC/ASPC) ; Levesque2, Kaili (HC/SC) ; Elmslie, Kim (PHAC/ASPC) ; Fortin2, Dany (PHAC/ASPC) ; Apse, Krista (PHAC/ASPC) ; Joyal, Martin (PHAC/ASPC) ; Brodie, Krista (PHAC/ASPC) ; Anderson3, Jennifer (PHAC/ASPC) ; Wiseman, Vicki (PHAC/ASPC) ; 'Pamela Ponic (PHAC/ASPC) (pamela.ponic@canada.ca)' ; Currie, Andrea (PHAC/ASPC) ; OPOCPHO Single Window / Guichet Unique BPBACSP (PHAC/ASPC) ; Charbonneau, Lise (PHAC/ASPC) ; McLeod, Robyn (PHAC/ASPC) ; Arnold, Eric (PHAC/ASPC)
Subject: Annotated Agenda Joint CDMH - Intergovernmental DMs Meeting Today @ 10:30 am
Good morning Iain and Theresa,
Please find attached the draft federal annotated agenda for this morning's joint IGA DMs- CDMH meeting. It is also under review by HC DM.
FPT Joint Meeting of Deputy Ministers of Health and Intergovernmental Affairs (Joint IGA) – Wednesday, December 9, 2020 (10:30-11:00am)

1) **Update on Regulatory Approvals – *for information/discussion***
   - DMs to receive an update on recent vaccine regulatory approvals from Health Canada.
     - DM Lucas will provide this update.
     - Iain, we have prepared brief remarks for you on continued dry run preparations and next steps over the next few weeks.

Dial-in Information (TBC):
Toll-Free Dial-In Number (Canada/US): 1-855-288-0982 or 1-855-244-8677
Participant Code: [redacted]
Thanks,
Kerry
C 613-618-0964

ATIA - 19(1)

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From: [redacted]
Sent: 2021-06-30 12:14 PM
To: Tam, Dr Theresa (PHAC/ASPC)
Cc: Ponic, Pamela (PHAC/ASPC); Ugnat, Anne-Marie (PHAC/ASPC)
Subject: Re: Invitation to join virtual Myocarditis Expert Panel on July 6 at 11 AM - 1 PM EST

Thank you for the kind invitation, delighted to participate. Happy to speak to all the questions except for # 5 and 6.

Thanks
[redacted]

[redacted] in Paediatric Translational Research
[redacted]
University of Toronto
Senior Scientist and Staff Rheumatologist
The Hospital for Sick Children

Providing and fostering excellence in scholarly clinical care for children with rheumatic disease.

From: "McLeod, Robyn (PHAC/ASPC)" on behalf of "Tam, Dr Theresa (PHAC/ASPC)"
Date: Wednesday, June 30, 2021 at 9:44 AM
To: "[redacted]"
Cc: "Ponic, Pamela (PHAC/ASPC)" , "Ugnat, Anne-Marie (PHAC/ASPC)"
Subject: Invitation to join virtual Myocarditis Expert Panel on July 6 at 11 AM - 1 PM EST

Dear [redacted]

On behalf the Public Health Agency of Canada (PHAC) and CanCOVID, I am writing to invite you to participate in a virtual science exchange on COVID-19 mRNA vaccine-associated myo/pericarditis risks to be held **Tuesday July 6th from 11-1pm EDT**. Please note that this is a private session with scientists at PHAC and not open to the public or media.

The intent of this session is to bring together clinical and scientific experts to speak to the current and emerging research on this topic. PHAC is partnering with CanCovid to help organize a forum that brings together government staff and scientists with national and international COVID experts to discuss the emerging evidence and considerations for public health policy. The format will be a round table discussion that provides all panel members the opportunity to share their expertise and advice for PHAC. The session will be moderated by [redacted] CanCOVID advisor on clinical research.

The draft questions to be addressed at this session are outlined in the attached. Please let us know which of these you would be prepared to speak to, and you are welcome to send 2-3 relevant papers you or others have published on this topic that will be shared with the larger group as background material.

Dr. Theresa Tam

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Dr. Theresa Tam, BMBS (UK), FRCPC
Chief Public Health Officer of Canada
Public Health Agency of Canada

Administratrice en chef de la santé publique du Canada
Agence de la santé publique du Canada
drtheresa.tam@canada.ca | 613-954-0594

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From: Namiesniowski, Tina (PHAC/ASPC)
Sent: 2020-08-18 7:21 PM
To: Dickson, Samantha M (HC/SC)
Cc: Tam, Dr Theresa (PHAC/ASPC); Lucas, Stephen (HC/SC); Kochhar, Harpreet (HC/SC); Rendall, Jennifer (PHAC/ASPC); White, Belinda (HC/SC); Thakkar, Bhavik (HC/SC); Levesque2, Kaili (HC/SC); Kropp2, Rhonda (PHAC/ASPC); Edwards, David K (HC/SC); Paquette2, Susie (HC/SC)
Subject: [redacted]

Thanks Samantha.

Sent from my iPhone

> On Aug 18, 2020, at 7:14 PM, Dickson, Samantha M (HC/SC) wrote:
>
> Hello,
> [redacted]
> Should you have any questions or wish to discuss, please let me know.
> Thanks.
> Samantha
> Samantha Maislin Dickson
> Executive Director and Senior General Counsel
> Department of Justice
> Health Legal Services / Government of Canada
> samantham.dickson@canada.ca / Tel: 613-957-3766
>
> Directrice exécutive et Avocate générale principale
> Ministère de la Justice
> Services juridiques de Santé / Gouvernement du Canada
> samantham.dickson@canada.ca / Tél: 613-957-3766
>
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From: [redacted]

Sent: 2020-08-05 1:30 PM

To: Tam, Dr Theresa (PHAC/ASPC)

Subject: Re: Reporting relationship - framework for a COVID-19 Immunization Strategy for Canada

Attachments: Framework for a National COVID-19 Immunization Strategy_July 2020.docx

---

Hi Theresa,

Given the announcement today related to APAs for a couple of mRNA vaccines, as I understand it, I thought I'd forward my thinking - albeit imperfect - on a framework for a COVID-19 Immunization Strategy that I mentioned to you and Kim. Even if I am not the person that ends up leading this, I trust it will be helpful to you all.

There are some key principles that will need to be agreed to across all Canadian jurisdictions - and adhered to - including as much standardization as possible across Canada in its execution - or there will be major challenges that can easily be foreseen.

[redacted]

I also am not sure how the Health Portfolio and FPT COVID-19 emergency response structures are currently organized and how this will fit - I believe it must, as buy-in will be critical. If the COVID-19 emergency response structures have been dissolved, then I assume whatever senior peace-time structures are in place would be the places to obtain the required engagement and buy-in.

As I previously advised you and Kim, I would require the full support of the PHAC to execute and report on this [redacted]

[redacted]

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As I also advised you and Kim during our conversation, [redacted]

If you can get back to me as soon as possible on some of these outstanding issues, that would be great. I would be more than pleased to video-conference with you and Kim once again if that is possible at your convenience.

As I indicated to you and Kim, [redacted] However, I would need to check on that with them.

Best, [redacted]

On Monday, August 3, 2020, 3:11:44 p.m. PDT, Tam, Dr Theresa (PHAC/ASPC) wrote:

Thanks [redacted]

We will give these questions some thought.

TT

Sent from my iPhone

> On Aug 3, 2020, at 18:02, [redacted] wrote:
>
> Hi Theresa,
> Thank you very much for following up with me. It is greatly appreciated.
>
> I have fleshed out a draft framework with elements of the proposed immunization strategy but I haven't had time to polish it up, and there are quite a few holes, given the unknowns related to the work of and interface with the vaccine task force (see below).
>
> As I indicated during our call, I have quite a lot on the go right now, including responses to multiple reviewer comments and [redacted] There also is quite a bit of work in the lead up to certification announcement on 25 August. I also am preparing

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[redacted] related to the impact of COVID-19 on immunization programs in our Region. I trust that the dust will settle on these and other activities over the next 2 to 3 weeks.
>
> I would like to give your reporting options some more thought and get back to you with a preferred option later this week. I also will send you the draft framework I have developed.
>
> Additionally, I am thinking that [redacted]
>
[redacted]
>
[redacted]
>
> So a few more questions for you to consider and I promise to get back to you on the reporting options later this week ... I hope that is acceptable to you and Kim.
>
> Best, [redacted]
>
> Sent from my iPhone
>
>>> On Aug 3, 2020, at 12:27 PM, Tam, Dr Theresa (PHAC/ASPC) <drtheresa.tam@canada.ca> wrote:
>> Hi there
>> Just a quick follow up [redacted]
>>
>> Kim is the Vice President lead in the COVID for vaccine program response, as head of the Infectious Disease Prevention and Control branch [redacted]
>> Tina Namiesniowski, President of PHAC [redacted] all VOs report to her. [redacted]
>> [redacted] Thoughts?
>> TT
>> Sent from my iPhone

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COVID-19 Immunization Strategy for Canada

"Make No Little Plans. they have no power to stir [the] blood and probably themselves will not be realised ..." Daniel Burnham, Chicago Architect (1816-1912)

Building on Canada's National Immunization Strategy, the Canada's COVID-19 immunization strategy should contain the following, interconnected components, and plan to leave a legacy of a strengthened national immunization strategy for Canada. It is based on experience delivering the pandemic H1N1 (2009) vaccine, seasonal influenza vaccines and large-scale immunization programs that have been implemented in response to communicable disease exposures and outbreaks. It must build on existing structures and processes, where possible, as it is challenging – some may say impossible - to create something completely new during an emergency. Project management support is essential to sequence and develop timelines for the activities required for successful execution. Finally, thought must be given to how and whether the COVID-19 Immunization Strategy will align with Canada's COVID-19 emergency response structure.

1) Vaccine development, acquisition and production strategy – a process is currently underway to acquire vaccine under the Vaccine Task Force. The outcome of this process will result in advance purchase agreement(s) for enough vaccine to immunize all Canadians with up to two doses of vaccine. The Chair of this group, or a member, should be engaging with the Chair of the COVID-19 immunization strategy group.
2) Vaccine clinical trials – the Canadian Immunization Research Network (CIRN) is currently planning clinical trials of candidate COVID-19 vaccines in Canada. The team lead should be engaged with the COVID-19 implementation strategy group.
3) Immunization recommendations – the National Advisory Committee on Immunization should make recommendations on vaccine use in Canada. The NACI should be providing advice to the CIRN on the target populations on whom new vaccine candidates should be tested for safety and immunogenicity.
4) Vaccine procurement process – this should be led by CIRID, in collaboration with Public Services and Procurement Canada on behalf the Vaccine Supply Working Group. The VSWG also should be planning and making recommendations on the auxiliary supply (eg, needles, syringes, etc), vaccine shipment and vaccine storage requirements.
5) Immunization registries – all Canadians receiving vaccine should be pre-registered in their provincial or territorial as potential recipients of a COVID-19. This will enable planning for procurement of the appropriate volume of vaccine for Canada. The administration of all vaccines should be recorded electronically, through a bar-coded product that is linked to the DIN supplied by Health Canada. This will be especially important given that many if not most Canadians will require two doses of vaccine and new COVID-19 vaccines will not be interchangeable.
6) Immunization program planning and implementation – who, where, when, why, how and so what ...

   Planning should be anticipated for the delivery of more than one product/type of COVID-19 vaccine. All vaccine delivery should be conducted by vaccine delivery agents who are able to comply with the minimum standards for the storage and administration of COVID-19 vaccine, including the appropriate infection prevention and control measures, in light of the risks of COVID-19 transmission associated with the provision of health care services during the

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pandemic. Priority groups for the receipt of vaccine **must** be standardized across Canada, as well as the timing of the implementation of priority group immunization. Planning should be anticipated for the delivery of more than one product/type of COVID-19 vaccine. Planning also should consider how, when and where each age group (preschool children, school-aged children, working age adults and seniors) and special populations (Canada's aboriginal peoples, migrants, refugees, persons in residential care, those who are incarcerated) will be reached.

7) Professional and public education and communication related to COVID-19 immunization – professional and public communication strategies should be developed and implemented as soon as possible to prepare for the eventual administration of a COVID-19 vaccine. Messaging and FAQs should include what we know, what we don't know and what we are doing about what we don't know as it pertains to the COVID-19 immunization program and should be aligned with global and regional messaging and need to be updated constantly. Following the procurement announcements, this should start with the announcement that a national COVID-19 immunization strategy is under development, along with the components of that strategy.
8) Surveillance for COVID-19 and vaccine-associated adverse events – building on the current national surveillance strategy for COVID-19, influenza and other respiratory virus surveillance platforms and adverse event following immunization (AEFI) surveillance systems, both passive and active, the goals and objectives of surveillance should be developed and appropriate systems implemented.
9) Management of AEFIs – building on existing national processes, signal identification and management and field investigation should be anticipated and strengthened. As immunization will be strongly encouraged, and perhaps required in certain settings, consideration should be given to the development of a national vaccine injury compensation scheme.
10) Evaluation and applied immunization research – in collaboration with the Canadian Institutes of Health Research, the COVID-19 immunization program should be monitored and evaluated, and a plan developed for this.

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From: Stewart, Iain (PHAC/ASPC)

Sent: 2021-06-07 8:04 PM

To: Bent, Stephen (PHAC/ASPC)

Cc: Rendall, Jennifer (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC); Parisien, Stéphanie (PHAC/ASPC)

Subject: Re: Vaccine injury compensation

I am glad to hear that it will be worked out on a case by case basis by expert panel

Sent from my iPhone

On Jun 7, 2021, at 7:24 PM, Bent, Stephen (PHAC/ASPC) wrote:

Hi Iain,

Here you go. Hope this answers your question:

There are four stages of the claims process.

a) **Eligibility** - this is assessed by RCGT based on key parameters we have set for the program, including: date of administration (on or after Dec 8th 2020), where it was administered (in Canada - with some exceptions for CF members and foreign service), and a Health Canada authorized product. The injury must be serious and permanent as well. If an individual is eligible to apply, the can go on to the next step. RCGT has no control over these parameters (they have been set by our policy).

b) **Application and Causality Assessment** - once a claim is determined to be eligible for the program, the applicant will submit the necessary information for RCGT to undertake a causality assessment (medical records, proof of vaccination etc.). RCGT is still designing this process, but it will likely involve 3 medical experts, which is what is done for the QC program. If causality is determined, the file will move to the determination of benefits stage.

c) **Determination of benefits** - Given RCGT is an independent 3rd party, they will have some latitude to design the compensation framework for the program, within the following parameters set out by Treasury Board in our Submission:

Financial support payments issued to beneficiaries by the third-party administrator will be based on existing and acceptable standards or schedules for injury, agreed upon by the Public Health Agency of Canada, and will include the following, as applicable:

ATIA - 20(1)(b)

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• income replacement indemnities up to a maximum of $100,000 per year;

• injury indemnities up to a maximum of $275,000;

• death benefits up to a maximum of $450,000;

• funeral costs up to a maximum of $7,000; and

• reimbursement of eligible costs including but not limited to, medical and rehabilitation costs otherwise not covered by public or private insurance or benefit programs.

Keep in mind- these up-to amounts are not what RCGT will necessarily pay. It is the ceiling for them. They will calibrate these benefits with the QC program, and other sectors (i.e. insurance industry).

The determination of benefits will be based on an assessment of degree of permanent injury. This too will be completed by medical experts drawing on international tools such as the American Medical Association Guide To Permanent Impairment.

d) **Appeal Process** – If an applicant is not satisfied with the causality assessment or determination of benefits, they will have access to an appeal process that uses different medical experts.

A word of caution. We accelerated RCGT's launch from [redacted] based on growing pressure to launch – RCGT is still working through their approach to causality and the compensation framework. The later will not be available for us to look at for a while [redacted] is the target date) - which is not problematic because it will take time for eligible applicants to submit their applications and go through the causality process. However, if we are asked "how much someone will get", our answer remains that it will be based on a case-by-case basis, within the types of benefits provided above.

We have also asked RCGT to prioritize [redacted]

Steve

-----Original Message-----
From: Stewart, Iain (PHAC/ASPC)
Sent: 2021-06-07 6:30 PM
To: Bent, Stephen (PHAC/ASPC)
Cc: Rendall, Jennifer (PHAC/ASPC)
Subject: Vaccine injury compensation

Stephen - who decides whether to accept a claim - do we have a medical board ? - and how is the amount paid out for a claim determined - is it a flat amount for standard kinds of unity or is it an expert panel decides based on the case?

Iain

Sent from my iPhone

ATIA - 20(1)(b)

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From: Elmslie, Kim (PHAC/ASPC)

Sent: 2021-02-09 9:59 AM

To: Stewart, Iain (PHAC/ASPC)

Cc: Rendall, Jennifer (PHAC/ASPC); Bent, Stephen (PHAC/ASPC); Romano, Anna (PHAC/ASPC)

Subject: [redacted]

[redacted]

3rd Party Delivers

- Proactive outreach to 10 companies / organizations. Continuing to follow up with others as contacts are identified.

[redacted]

- Solicitation review committee composition under development. Work on assessment tool for proposals ongoing.

FPT

- All P/Ts have written confirming op-in to national program (except Quebec)
- E-mail to P/T-identified officials on Monday advising them of forthcoming solicitation launch. Update meeting with same officials the week of Feb 15th.
- Update to be provided at SAC on Thursday and CDMH on Friday.
- Correspondence to be sent to SK (VP-level) clarifying information in its letter regarding individual's continued right to litigation.

Central Agencies

- Close ongoing collaboration with TBS
- Update brief to PCO provided on Thursday Feb 4th

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Key Upcoming Milestones

- Wed Feb 10th – Solicitation Opens and ongoing engagement with applicants as req'd
- [redacted]
- Wed Feb 24th – Solicitation Closes
- [redacted]
- Wed March 3rd – Review Committee Selects 3rd Party
- Wed March 17th – Signed Contribution Agreement With 3rd Party Deliverer
- TBD – Announcement of 3rd Party Deliverer

Kimberly Elmslie

Vice-President/vice-président

Infectious Disease Prevention and Control Branch/Direction-générale de la prévention et du contrôlée des maladies infectieuses

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From: Salvadori, Marina (PHAC/ASPC)
Sent: 2020-12-11 8:58 AM
To: Tam, Dr Theresa (PHAC/ASPC); Njoo, Howard (PHAC/ASPC)
Cc: Ponic, Pamela (PHAC/ASPC); Macey, Jeannette (PHAC/ASPC); Killen, Marita (PHAC/ASPC); Rendall, Jennifer (PHAC/ASPC)
Subject: Vaccine Compensation Editorial from jane Philpott et at in the Globe

---

I am sending you this in case the original heading did not catch your eye. It is a call for vaccine injury compensation form kieran Moore and jane Philpott
Marina

From: Campagna, Domenic (HC/SC) **On Behalf Of** Media Monitoring / Suivi des Medias (HC/SC)
Sent: 2020-12-11 7:46 AM
Subject: Opinion: The Globe and Mail: Canada needs to prepare for rare but serious health problems resulting from vaccination
Distribution Group / Groupe de distribution : HC.F PEIA COVID19 / COVID19 AREP F.SC; HC.F PEIA Ministers Monitoring / Surveillance des medias ministre AREP F.SC; HC.F PEIA Pharmaceuticals Biologics and Genetic Therapies / Pharmaceutiques biologiques et therapies genetiques AREP F.SC; HC.F PEIA Health Care / Soins de sante AREP F.SC

December 10, 2020

Canada needs to prepare for rare but serious health problems resulting from vaccination

SOURCE : The Globe and Mail, Jane Philpott, Kieran Moore & Ethan Toumishey

We have to use all the tools at our disposal to promote high COVID-19 vaccination rates across the country. It will take about 25 million immune Canadians to lift the patchwork of public health restrictions blanketing our provinces and territories. Here, we recommend an important step Canada should take to ensure that all Canadians who willingly get immunized for the collective benefit have clear medical and legal pathways to address those very rare, unintended or unexpected outcomes after immunization.

Adverse events following immunization (AEFIs) include any unwanted or unexpected health effects that happen after a person receives a vaccine. AEFIs are often mild and, most of the time, clear up quickly and completely. Most Canadians are familiar with mild AEFIs such as redness and swelling at the injection site, headache or fever. Though exceedingly rare, more severe health effects can occur after vaccination such as allergic reactions, neurologic events such as seizures, and, in extremely rare cases, death. We are seeing this play out in the U.K., as adverse reactions are discovered in parallel with the delivery of the COVID-19 vaccine.

The current legal recourse mechanism, outside of Quebec, requires claimants who have suffered injury to demonstrate fault in order for a compensatory award to be granted. In other words, the provider or distributor (often including the practitioner who gave the injection) of the vaccine must be proved to have violated a standard of practice. Unfortunately, those rare but serious AEFIs can occur even when appropriate protocols are followed. People suffering severe AEFIs are left to assume the costs of legal fees, lost wages, uninsured medical services and rehabilitation supports.

No-fault compensation programs are one means by which compensation could be provided differently to better support Canadians. Globally, there are many countries that have national no-fault compensation programs for AEFIs, but Canada is not one of them. In fact, Canada is the only Group of Seven country that has not implemented a national program, though, within Canada, Quebec has had a program for vaccine injury compensation since 1985.

Typically, no-fault compensation programs are the responsibility of a government body that assesses and decides individual cases. Claimants access the process after submission of an AEFI report from an attending physician. Claimants do not require legal representation. A compensation decision is based on an administrative review of eligibility criteria and an independent physician assessment.

In the context of the COVID-19 pandemic, we are concerned that, given the anticipated scale of the COVID-19 immunization campaign and new vaccine technologies employed, mass immunization may result in a small number of Canadians experiencing serious AEFIs, despite adherence to best practices. While AEFIs are possible with routine immunizations, pandemic situations are unique with respect to the speed and scale with which vaccine technologies are developed and distributed. Rare serious AEFIs may not be captured during phases of clinical trials because it may require very large numbers of the population to be immunized for AEFIs to manifest.

The anticipated incidence of serious AEFIs can be estimated at 1 in one million immunizations. Serious adverse outcomes are exceedingly more common with COVID-19 infection itself, but the potential health consequences of adverse events following immunization borne by the few will be for our collective benefit in stopping the deadly spread of the virus. Operating under this estimate, we anticipate 25 Canadians may suffer a serious health outcome following COVID-19 vaccination, or 0.1 per 100,000 doses.

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Jurisdictions with no-fault compensation programs have reported cost-savings. By avoiding legal fees, evidence suggests millions of dollars have been saved. In no-fault systems, compensation is needs-based and not punitive. This has allowed for faster payments, quicker resolution and higher levels of complainant satisfaction. A fault-based system is an obstacle to those few who do suffer harm and a concern for those providers who administer the vaccine in good faith.

An appropriate, equitable and fair compensation system with a transparent accountability process for monitoring potential AEFIs associated with COVID-19 immunization could increase public confidence in vaccines and promote uptake. Though none of us want to consider adverse vaccine-related health outcomes while we are enduring the COVID-19 pandemic, given the high vaccination numbers we hope to attain, due diligence requires Canada to ensure no one is left behind as we plan for the vaccine rollout and work to end the pandemic.

URL : https://www.theglobeandmail.com/opinion/article-canada-needs-to-prepare-for-rare-but-serious-health-problems-resulting/

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ATIA - 21(1)(a)

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From: Salvadori, Marina (PHAC/ASPC)
Sent: 2020-10-25 6:25 PM
To: Tam, Dr Theresa (PHAC/ASPC); Elmslie, Kim (PHAC/ASPC)
Subject: Vaccine compensation - let's find a new name

I've been thinking quite a bit [redacted] This part of vaccination is not my specialty per se, but I think we need to find a better name now. I can't find much in the literature, or else I don't know how to search for it.
I suggest:
Immunization serious consequence insurance program.

There is literature that immunization is far less charged than the word vaccine
We can't use "adverse event" as that means something in the vaccine world [redacted]
And it is a compensation program, but I think the concept is akin to insurance, which makes the public immediately jump to an appropriate concept.

What do you think? I'm not in any way attached to it, just thinking about it.
Marina

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From: Salvadori, Marina (PHAC/ASPC)
Sent: 2020-10-18 2:14 PM
To: Tam, Dr Theresa (PHAC/ASPC)
Cc: Warshawsky, Bryna (PHAC/ASPC)
Subject: Vaccine injury compensation program resources

Bryna and I tried to find some fast things to get you up to speed. Let us know if you need something different or a more fulsome analysis. See below.

Possible downsides from one reference:

There are also risks and problems attached to no fault compensation schemes. In some countries, parents have utilized the schemes to seek financial recompense for disability or disease of children that is not caused by vaccination, and sometimes compensation is awarded in a way that does not accord with robust medical nor epidemiological evidence [24], [25]. Anti-vaccination activists can also use schemes to emphasise vaccine injuries, ignoring the fact that passive surveillance systems for adverse events following immunisation list adverse events prior to the establishment of causation [26]. Therefore, schemes should adhere to the WHO recommendations regarding establishing causality for AEFIs [27], with mechanisms for expert assessment and agreed criteria for compensation.

I also read a fascinating article on possible downsides in this pandemic – The US compensation system is set up to incentivize manufacturers and protect them from liability. In this case, the public already distrusts the regulators, so disincentivizing the manufacturer to have responsibility for their product could lead to more public distrust.

I can find no fulsome analysis of this issue for COVID-19 specifically.

General synopsis from Bryna below. The first one is the one you had in your office – short and sweet. (*but there were two errors in it, which should have been picked up in peer review.)*

Vaccine Injury Compensation Programs and the situation in Québec (Dubé E, Gagnon E, MacDonald N, Harmon S, Hapuhennedige S – published September 2020)

Very good overview and quick read.

- 19 jurisdictions have Vaccine Injury Compensation (VIC) Programs worldwide (mostly high income countries) (based on international programmes referred to below by Looker and Kelly)

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  - Summarizes some of the elements related to administration, funding, eligibility, process, standard of proof, elements of compensation, litigation rights
- Describes the arguments supporting VIC programs: biological (rare adverse events do occur after vaccination); ethical (vaccines benefit all), legal and practical (litigation is costly and uncertain)
- General concerns include: costs of these programs, the difficulties with causality assessment (i.e. determining whether there is a causal relationship between a vaccine and a specific injury) and the concern that these programs can decrease public trust in vaccines and fuel anti-vaccination movements
- The Quebec system has been in place since 1985:
  - The process is as follow: have three years to file the claim after the injury, reviewed by an external committee of experts in vaccinology, Minister of Health and Social Services makes decision, *Société de l'assurance automobile du Québec* determines the compensation and pays
  - As of April 1, 2018, 228 claims have been submitted; 187 met admissibility criteria, 43 claims were accepted and $5.49 million in compensation paid
  - Usually 3 to 5 claims per year but 11, 16, 9 and 28 in 2009 and the three years following the H1N1pdm09 vaccination campaign

No-fault compensation following adverse events attributed to vaccination: a review of international programmes (Looker C and Kelly H – published in 2011)

- Determined that 19 countries had Vaccine Injury Compensation programs (note update below from WHO)
- Discusses the elements of the programs with respect to administration and funding, eligibility/vaccines covered, process and decision making, standard of proof, elements of compensation, litigation rights

World Health Organization (January 2019)

Identified 25 WHO Member states with Vaccine Injury Compensation Programs

United States Vaccine Injury Compensation Program

- Has been in place since the 1980s
- Various web pages describe the program in detail - how it works, what vaccines and injuries are compensable.
- From 1988 to October 1, 2020, over 22,272 petitions have been filed; 19,282 adjudicated, 7,611 determined to be compensable 11,671 dismissed; compensation at $4.4 billion

ATIA - 19(1)

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From: Begin, Martin (HC/SC) on behalf of CPAB MEDIA RELATIONS / RELATIONS AVEC LES MEDIAS DGCAP (HC/SC)
Sent: 2021-03-15 10:13 AM
Cc: Begin, Martin (FIN)
Subject: *FYI - Closing with factual response * (CTV [redacted] Vaccine injury compensation program

---

Good morning

Media Relations has received a request from CTV about the Vaccine injury compensation program. The reporter wants to know if there has been an update. The CIRID-drafted response is quite factual and we plan to send it to the reporter **at noon** today. Please let me know if there are any concerns.

Media/Reporter: CTV / [redacted]
Date Received: March 11, 11:30
Deadline to reporter: March 15
Impact: MEDIUM (2)
Complexity: MEDIUM (2)

Question and answer

Do you have any update on the vaccine injury compensation program discussed late 2020? Can you confirm if there is a request for proposal to establish such a program and any deadlines involved?

The Government of Canada is seeking to select an experienced third party to administer the pan-Canadian no-fault vaccine injury support program (VISP) through a contribution agreement. An open call for proposals to identify the third party was launched on February 10, and closed on February 24, 2021. The funding opportunity was posted on the Public Health Agency of Canada's (PHAC) Funding Opportunities page on Canada.ca. The solicitation, which is now closed, can be viewed here.

PHAC is currently evaluating the proposals received. More details on the program will be provided when available.

Approvec by:
Stephen Bent, CIRID A/DG (approved)
Martin Bégin, A/Chief, Media Relations
Louise Payette, MRMS Director (approved)

Martin Bégin
(he, him | *il, lui*)
Communications Executive, Media Relations | *Gestionnaire des communications, relations avec les médias*
Health Canada and the Public Health Agency of Canada |*Santé Canada et l'Agence de la santé publique du Canada*
Government of Canada | *Gouvernement du Canada*
Tel: 343-572-0219

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sara.mackenzie@canada.ca

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Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE
April 20, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE:
NS:
NB:
QC:
ON:
MB:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Melanie Knight
HC/BRDD: Robert Pless
VVWG: Amanda Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
PHAC: Heidi Rodger, Simon Côté, Natalia Abraham, Sean Meredith, Tony Walsworth, Kelsey Young, Bryna Warshawsky

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
NL: [redacted]
PE:
NS:
QC:
ON:
MB:
SK:
AB:
YK:
NT:
NU:

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ATIA-15(1) - I.A
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Invited Participants:
National Defence: Marie-Christine LaMontagne, Julie Nadeau
Correctional Service Canada: Jennifer Morse

VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committees and reminded members that PHAC will be hosting a webinar for health care providers on Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) this week, with the English session taking place on April 21, 2021 from 1:30 – 2:00 PM EST and the French session taking place on April 23, 2021 from 1:30 – 2:00 PM EST. Erin (CIC Federal Co-Chair) advised members that the CIC Secretariat circulated an embargoed copy of NACI's recommendations on the use of COVID-19 vaccines to CIC members, which was updated to include VITT evidence, earlier this morning. NACI is hoping to post the guidance online by 2:00 PM EST today, but the committee is currently reviewing one of the data tables and if changes are made, CIC members will receive a new embargoed copy of the guidance. Erin (CIC Federal Co-Chair) informed members that invitations for the upcoming Summit that will be hosted by PHAC on May 5, 2021 were sent out to ADM-level PT representatives on April 21, 2021, and that PHAC is looking for four jurisdictions to provide a brief five minute presentation on the theme of delivery, efficiency, and throughput.

2. Update on Procurement of 1mL Syringes

Heidi Rodger (PHAC) informed the committees that, to date, [redacted] syringes have been distributed to provinces. A flight carrying [redacted] 1mL syringes is expected to arrive at the Toronto airport on the evening of April 20, 2021, and an additional [redacted] are expected to arrive in Toronto on May 1, 2021. PHAC is still awaiting confirmation on the last couple of flights that will round out the [redacted]

The first delivery of ultra low dead space needles [redacted] are expected to arrive in early May 2021. Heidi (PHAC) noted that PHAC has procured enough 1mL LDV syringes to support the increased number of Pfizer doses that are expected to arrive over the next couple of months.

3. COVID-19 Vaccine Logistics Update

Simon Côté (PHAC) provided the weekly COVID-19 vaccine logistics update, noting that over 13.4M doses of COVID-19 vaccine have been distributed to FPTs. Members were advised that there are only Pfizer deliveries for the week of April 19, 2021, which started on April 19, 2021 and are expected to be completed by April 21, 2021. Simon (PHAC) noted that all of the Pfizer shipment numbers for May 2021 have been adjusted for the new allocations.

PHAC sent the updated Moderna allocation tables to FPTs on April 16, 2021, and sent the updated Pfizer allocation tables to FPTs on April 19, 2021. Deadlines for the submissions of request for orders were included in the emails that went out, and members are encouraged to contact the NOC if they have any questions. Members were advised that PHAC had a call with Moderna on the morning of April 20, 2021 and they confirmed that the 650,400 doses for the week of April 26, 2021 can be picked up the morning of April 27, 2021, with distribution to FPTs starting on April 29, 2021. If deliveries are not completed by the afternoon of April 30, 2021, then deliveries will continue the Monday of the following week, however, PHAC is hopeful that the original timeline can be adhered to.

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BC noted that in the original slide set that was provided to members from Heather Deehan (PHAC) and through the APAs, the AstraZeneca commitment was around 20M doses. BC asked if there is any information about future plans for the use of AstraZeneca vaccines. Milan Patel (PHAC) replied that PHAC does have notional numbers from AstraZeneca starting in June 2021. This information was received from PSPC the week of April 12, 2021, and Milan (PHAC) committed to working with colleagues to make this information available to PTs, keeping in mind that it's still notional and doesn't start until June 2021 as of right now.

MB asked if there are any discussions regarding purchasing more AstraZeneca doses from the U.S. Milan (PHAC) replied that PHAC is aware of ongoing discussions at the diplomatic level, including the Prime Minister level, to see how quickly some of the U.S. surplus vaccine can be moved to Canada. Milan (PHAC) noted that as per reports in the media, the U.S. is reaching a saturation point as they have gone down to the 20 year age range in their vaccine roll-out.

4. COVID-19 Vaccine Wastage & Inventory Reporting Processes

Sean Meredith (PHAC) and Tony Walsworth (PHAC) provided an overview of the new process for reporting COVID-19 vaccine wastage and inventory. Sean (PHAC) advised members that there are numerous variables that go into manufacture filling and that if PTs are withdrawing more or less than 6 doses per vial of Pfizer vaccine, those doses do not need to be thrown out – they're still viable pending professional judgment. Tony (PHAC) informed members that given feedback that has been received from various FPTs about how the current process for reporting wastage and reporting is difficult and burdensome, PHAC has made some changes to the process and is now asking for cumulative open and closed vial wastage numbers.

MB and SK both flagged that the wastage reports that they submit do not contain all of their wastage.

BC suggested that the NOC survey PTs to determine the accuracy of the information that they're receiving with regards to COVID-19 vaccine wastage and inventory to determine if the sum total is being captured.

5. Update on the Case Finding Definition for Thrombosis with Thrombocytopenia Syndrome (TTS)

Natalia Abraham (PHAC) provided an update on the case finding definition for TTS, noting that the Brighton Collaboration released a new draft interim case definition on April 19, 2021. Natalia (PHAC) then reviewed the changes that were made since she last presented the draft case finding definition, and added that Canada will need to consider if it wants to align with this particular international standard.

BC asked at which table this decision will be made. Susanna Ogunnaike-Cooke (PHAC) replied that she believes it will be SAC, but that whatever is brought forward to SAC will be informed by VWWG and CIC so PHAC would like to hear feedback from members. BC asked if Susanna's (PHAC) team will be sending out a proposal for members to review. Susanna (PHAC) confirmed yes.

QC commented, with regards to removing the PF4 antibody status as a criteria, that this is currently under discussion in QC but some of the experts that their province have consulted with are not in agreement with this move by the Brighton Collaboration. QC advised that they wanted to flag that PHAC can expect this type of comment to come through the other consultation processes for the Canadian definition.

6. NACI Update on AstraZeneca

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Kelsey Young (NACI Secretariat) provided an update on NACI's recommendations for the use of AstraZeneca COVID-19 vaccine. Kelsey (NACI Secretariat) informed members that the program pause that was recommended by NACI in late March 2021 was based on the age range for the majority of cases at that time, and that the new updated guidance is based on Health Canada's most recent safety assessment, current Canadian epidemiology, availability of mRNA vaccines, projected supply of vaccine, and an EEFA assessment. Kelsey (NACI Secretariat) highlighted the various assumptions and limitations of the analysis that was used in NACI's benefit-risk assessment, which was based on national COVID-19 surveillance data, and informed members that NACI chose to recommend that the AstraZeneca COVID-19 vaccine may be offered to individuals without contraindications in select age ranges in areas where COVID-19 activity is high or very high only if the individual dose not wish to wait for an mRNA vaccine and if all four conditions apply (details of the conditions can be found on page 7 of the guidance). NACI also mentioned that AstraZeneca should not be used in areas with very low, low, or moderate COVID-19 activity. Kelsey (NACI Secretariat) noted that NACI members did discuss that a simple age limit would be easier to implement, however, it was decided that a blanket age range wouldn't be the best way to optimize the use of this vaccine in Canada.

MB asked, when PTs are calculating high vs very high incidence areas, if the greater than or equal to 3 COVID-19 cases per 10,000 is for the overall population, or for a specific age group (e.g. individuals 50 years of age and older). Kelsey (NACI Secretariat) replied that it's the population level daily incidence and not within a specific age group.

7. Supply Allocation

Bryna Warshawsky (PHAC) provided an overview of when each age cohort in Canada will be able to be offered vaccine based on projected supply of mRNA vaccines, noting that Canada should be able to vaccinate everyone with their first dose somewhere near the beginning of June 2021. Bryna (PHAC) sought feedback from PTs on whether they have done this calculation within their own jurisdiction, and if they are communicating this information out based on the various age cohorts. Bryna (PHAC) also emphasized the importance of communicating this information to the public if PTs have done their own calculations given that part of the decision-making process for the AstraZeneca vaccine depends on when an individual would be eligible for an mRNA vaccine. Heather Deehan (PHAC) advised members that she would work with Bryna (PHAC) to update the slide deck before it is shared with members given that PHAC is meeting with Moderna on April 21, 2021 to discuss delivery timelines for the anticipated 4.9M doses coming in May 2021 and 4.5M doses coming in June 2021.

AB asked if this modeling will be communicated out to PTs or publicly. Bryna (PHAC) replied that PHAC will need to update the slide set and ensure that the numbers align before it can be circulated to members. AB asked for confirmation that there is no intention to make public messaging based on this modelling. Bryna (PHAC) confirmed no.

ISC commented that this item would be a good presentation at the upcoming FPTII Summit.

8. Roundtable

Members were asked to comment on the following questions:

Q1 – What is your jurisdiction's program/plan for COVID-19 immunization of:

- pregnant women; and
- pediatric age groups below 18 years of age including clinically vulnerable 12+.

Q2 – Is your jurisdiction offering specific clinics for African Canadians? If so, can you please share any details regarding these clinics.

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Q3 – What age range is your jurisdiction at this week with regards to the COVID-19 vaccine rollout for the general population?

Q4 – How is your jurisdiction assuring that the remote/isolated Indigenous communities they serve have access to HCP and Patient information materials?

Q5 – What is your jurisdiction's policy/procedure for providing second dose of COVID-19 vaccine when client has received their first dose in a different jurisdiction (e.g. U.S.) but does not have a record of immunization? Is written documentation required before providing the second dose?

YK replied as follows:

Q1 – YK has been encouraging pregnant women to get immunized with the messaging that they should talk to their HCP if they have questions, and also noted that they have a one-pager that clinics can provide. YK has immunized a few pediatric individuals below the age of 18 that are critically vulnerable on a case by case basis and based on a recommendation from a specialist.

Q2 – YK is not offering specific clinics for African Canadians as all individuals over the age of 18 are eligible to be vaccinated.

Q3 – YK is currently immunizing individuals 18 years of age and older throughout the territory and have been fortunate to be at that stage for a while now.

Q4 – When YK did their initial COVID-19 vaccine roll-out with mobile clinics, the territory set up community meetings with Indigenous groups who are able to communicate that information out and do mail-outs.

Q5 – YK is trying to ensure that individuals have their first dose record if it was received in a different PT, and then trying to complete the series with a similar type of vaccine as the first dose. If the individual does not have a record but can confirm the type of vaccine they received for their first dose (e.g. mRNA), then YK would probably take their word for it. Otherwise, it would be on a case by case basis and YK might have to restart the series.

NT replied as follows:

Q1 – At the beginning of NT's vaccine roll-out, NT's territorial medical director recommended to offer vaccine to pregnant women as long as they received a risk benefit discussion, so that was built into NT's FIT to immunize proposal. If individuals in pediatric age groups below 18 years of age are healthy, then NT is generally waiting for the clinical trials to be completed for Moderna in this age group before immunizing. However, if the individual is critically vulnerable, NT has referred them to a pediatric specialist who weighed the risks and benefits.

Q2 – NT did more of a risk-based and age-based grouping and did not offer specific clinics for African Canadians.

Q3 – NT is currently immunizing individuals 18 years of age and older and has been since mid-March 2021.

Q4 – NT developed a detailed communications plan in December 2020 and met with Indigenous leaders prior to their COVID-19 vaccine roll-out. Some of the key requests included that communities had lead time to have the opportunity to have vaccine questions answered orally and in written communication

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ahead of the vaccination teams' arrival in the communities, as well as specific information for elders in addition to some other issues. NT translated all of their information products into all 11 languages of NT. Some concerns were raised that that information wasn't provided in the different dialects of the Indigenous languages, and NT held a terminology workshop as a result. NT is evaluating their communications plan and going into more details for vaccine hesitancy. They have gone out to remote Indigenous communities a second and third time now to offer vaccine. They have also done door knockers, sent nurses in ahead of time and did Q&A sessions on radio shows in Indigenous languages.

Q5 – NT is following routine protocols and procedures for this, and they do require some sort of written documentation (e.g. immunization card) with the individual's name, the vaccine they received, and the date they received it if possible, but NT is not requiring a digitalized vaccine passport.

NU replied as follows:

Q1 – NU has been encouraging pregnant women to be vaccinated with the Moderna COVID-19 vaccine since the beginning of their campaign, and noted that they do have a specific document to assist HCPs when having risk benefit conversations with pregnant women and to ensure that they are fully informed before making a decision to be vaccinated or not. NU has not had any requests to vaccinate pediatric patients but noted that requests would be reviewed on case by case basis, and NU is also keeping an eye on the clinical trials in those populations.

Q2 – This question does not apply to NU's situation – for the most part, their model has been mass vaccination clinics for individuals over the age of 18, but they did do risk-based immunization in some of their larger communities.

Q3 – NU has done a fair amount of work to ensure that individuals have good access to materials about vaccination in their language, specifically for the Moderna COVID-19 vaccine. NU translated their documents in all four languages of their territory from the beginning, and have had some paper materials available to ensure fair access to those who do not have a computer or the internet. NU noted that there are sometimes differences in regional dialects and that interpreters have been assisting to ensure that the information is disseminated and well-understood.

NL replied as follows:

Q1 – NL has been encouraging pregnant women to receive the COVID-19 vaccine since the start, and they do provide some information on the risk benefit approach and if possible to have a conversation with the HCP, especially if it is a higher risk pregnancy. Currently, only pregnant women who fall into an eligible population (e.g. HCWs) are able to receive the vaccine, but the prioritization of pregnant women is under discussion. Pediatric age groups are done on a case by case basis and NL is aware of two 15 year olds that met the criteria and were vaccinated.

Q2 – NL is not currently offering specific clinics for African Canadians, and noted vaccine would be provided to individuals of any ethnicity as long as they fall within the age cohort.

Q3 – NL is currently immunizing adults aged 65+ in the general population.

Q4 – NL has developed some information materials for Indigenous communities and have also been in discussion with these communities since the start.

Q5 – NL will honour a paper record if it shows the vaccine that the individual received and when they received it. NL is not seeing a whole lot of people needing their second dose at this time. Given that NL has a large rotational worker population which includes workers who work outside of the country, their

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biggest concern would be trying to handle if a worker was immunized with a vaccine that is currently not authorized for use within Canada. NL would try to honour the second dose if possible.

PE replied as follows:

Q1 – PE noted their response is the same as NL's, and that they are discussing prioritizing pregnant women however they are not currently doing so. PE is now offering COVID-19 vaccines to pediatric age groups 16+ with underlying medical conditions and all eligible members of their household.

Q2 – PE is not currently offering specific clinics for African Canadians.

Q3 – As of April 19, 2021, PE is immunizing adults aged 50-54 years.

Q4 – PE does not have any remote or isolated Indigenous communities but noted that there are two reserves on PE and they have access to all of the materials.

Q5 – PE hasn't had anyone show up yet requesting a second dose with no record of their first dose, but PE would request documentation of the first dose before providing the second dose.

NB replied as follows:

Q1 – NB made a decision today that all pregnant women will be immunized as part of a priority group (this has not been made public yet). NB has no plans to immunize individuals below the approved age for vaccines unless the individual is under 18 years of age and risk assessment is done – this would be done on a case by case basis and would also need to go to cabinet.

Q2 – NB is not offering specific clinics for African Canadians.

Q3 – As of April 20, 2021, NB is immunizing adults aged 65+ (this information was provided by NB following the meeting, as they had originally advised that they were currently immunizing adults aged 70+.) NB is immunizing First Nations individuals 16+, individuals with 3+ select complex health conditions aged 40+, all ages for HCWs and for workers who regularly travel across the border, and adults aged 55+ for AstraZeneca. NB is also immunizing corrections and homeless shelters at this time.

Q4 – NB noted that all of their Indigenous communities have a health centre and all of their information can be found on their provinces website. They have shared First Nations toolkits and all First Nations communities have held clinics that were supported by Public Health.

Q5 – NB noted that they are not aware that this is an issue and offered to circle back and send information to the CIC Secretariat following the meeting.

NS replied as follows:

Q1 – NS is very much using an age-based approach for their vaccine roll-out and the immunization of pregnant women alone is not being contemplated for prioritization for vaccine at this point in time. NS is also not aware of any plans to prioritize the pediatric age group below 18 years of age.

Q2 – NS noted that they raised this question and that they are currently hosting speciality clinics for African Canadians in collaboration with African Nova Scotian leaders, and have set up clinics in areas with denser populations.

Q3 – NS just opened up bookings for adults aged 60+ on April 19, 2021.

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Q4 – NS does not have remote and isolated communities but have developed additional HCP and patient information materials which would be accessible through the consent process. HCPs also have access to an FAQ document that NS has prepared as well.

Q5 – NS noted that there is a process in development to manage second doses, but could not comment on what would happen if there was no written documentation.

QC replied as follows:

Q1 – QC is vaccinating pregnant women if they meet another criteria, for example HCWs or some essential workers including teachers. QC has also started their first group of severe chronic conditions which is hospital-based. QC noted the same goes for pediatric individuals aged 16-18 years. Pediatric hospitals are not included in the rollout however, if they have a severe chronic condition that is hospital based, there was a possibility of access to a vaccines. For example, if you have a child receiving treatment for cancer, they could probably access the vaccine. QC has not had many requests yet with regards to pediatric individuals aged 12-18 years with severe underlying conditions, and noted that Pfizer could be offered to individuals aged 12-18 years if a risk benefit assessment is provided however it is not a government issued recommendation or priority.

Q2 – QC is not offering specific clinics for African Canadians but noted that they are having discussions on strategies to better reach various communities, and that there have been some strategies already used in Montreal and other areas to improve awareness about the importance of immunization.

Q3 – QC is currently immunizing adults aged 60+. QC will be immunizing adults aged 45+ for AstraZeneca, and noted that a few 18-59 year olds are currently being offered immunization due to either very high risk chronic conditions, essential workers, or First Nations individuals.

Q4 – QC used various approaches including the engagement of Indigenous leaders prior to launching their vaccine campaign, having extra HCW teams that flew to remote and isolated Indigenous communities to help, and community engagement was done prior to immunizers flying up North to optimize vaccine use on the date that the clinics were planned.

Q5 – QC would normally request written proof but could not comment on how immunizers would handle someone showing up without proof of their first dose. QC added that when you go into their system, it will give you the first dose appointment even if someone has already received a first dose (e.g. snowbirds who received their first dose elsewhere).

ON replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – [redacted]

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vaccinations right now and there was just an announcement that some pharmacies will be providing vaccinations 24/7.

Q4 – [redacted]

Q5 – ON believes this would be handled on a case by case basis but could not confirm.

Erin Henry (CIC Federal Co-Chair) advised members that NACI is currently looking at new data that was provided yesterday and that it seems that they will change their recommendation, so PHAC hopes to have an updated statement for CIC members tomorrow with the new recommendation.

MB replied as follows:

Q1 – MB was unsure if they will be looking at prioritization for pregnant women but noted that right now, pregnant women require consults with HCPs and MB has an enhanced process to get them through the consent process. With regards to pediatric age groups, MB's current program is individuals aged 18+, but they noted that there have been a couple of individuals that were immunized under the age of 18 but could not confirm if it was because they are critically vulnerable. MB will be reviewing the clinical trial data for this age group as it becomes available.

Q2 – MB is looking at doing some high risk clinics but is not offering specific clinics for African Canadians.

Q3 – MB is currently immunizing adults aged 55+ (First Nations individuals 20 years younger than the age cohort for the general population are also eligible) and noted that they are probably going down by 1-2 years this week. MB is offering AstraZeneca to adults aged 40+ as of April 19, 2021.MB is looking to start vaccinating high risk communities 18+ this week but that hasn't been rolled out yet – more details to come.

Q4 – All of MB's information is available online for providers to download and also made available at the points of immunization.

Q5 – MB does not have a policy with regards to second doses – their current process requires documentation but MB was unsure if they've come across this scenario yet.

Erin (CIC Federal Co-Chair) reminded members that the NACI announcement is confidential and that the press conference slated for 1:15 PM EST today was cancelled. MB asked if the public release of the recommendation will be delayed. Erin (CIC Federal Co-Chair) confirmed yes.

SK replied as follows:

Q1 – SK is targeting pregnant women for COVID-19 vaccination as a separate group and they are currently eligible for vaccination. SK is targeting individuals aged 16 and 17 that are considered clinically vulnerable.

Q2 – SK is not offering specific clinics for African Canadians.

Q3 – SK is currently immunizing adults aged 40-49 years and all other age groups above this age range continue to be eligible.

Q4 – SK provided the following response via email to the CIC Secretariat following the call:

- Resources are posted online but there may be internet connectivity issues

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- ISC holds weekly calls with Health Directors and nurses to provide updates on general vaccine and COVID information.
- Material is sent out via email before and after the meetings
- Local health leadership works collaboratively with other First Nation health, regional health and provincial health organizations to obtain information.
- For patients information re: COVID vaccines is sent with the vaccine so they have hard copies.
- Health information is also disseminated through local radio channels using English and the local FN languages to reach a wider audience, also local newspapers and Facebook.
- Patients also access information from the HCP.
- One of the SK First Nation health authorities has their own website with information; they also have a weekly COVID-19 meeting and provide regular updates to HCPs

Q5 – SK noted that they raised this question.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – [redacted]

Q4 – [redacted]

Q5 – [redacted]

BC replied as follows:

Q1 – Right now, the clinically vulnerable program has rolled out for individuals aged 16+ (letters went out for receipt by April 15, 2021).

Q2 – BC is not offering specific clinics for African Canadians but noted that they have had specific clinics for cultural communities largely in South Asian communities in high transmission areas.

Q3 – BC is currently immunizing adults aged 63+ (First Nations individuals 15 years younger than the age cohort for the general population are also eligible), and adults aged 40+ for AstraZeneca and this program is focusing on several communities in BC with high COVID-19 transmission right now.

Q4 – BC noted that Indigenous populations were vaccinated very early as they were prioritized in Phase 1, so some of the materials that BC has now for Indigenous communities weren't available at the time. The FNHA was very instrumental in operationalizing those programs.

Q5 – Similar to what has been discussed, if the verbal history is sufficiently convincing then BC would accept it and provide the second dose, however, a written record is preferable.

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Erin (CIC Federal Co-Chair) informed members that NACI will likely not be ready for an announcement on April 21, 2021, but that it will be coming this week.

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CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE
April 27, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE:
NS:
NB:
QC:
ON:
MB:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Chantale Chisholm, Mark Sagan
HC/BRDD: Robert Pless
VVWG: [redacted]
CIRC: Nicolas Gilbert, [redacted]
PHAC: Heidi Rodger, Simon Côté, Natalia Abraham, Susanna Ogunnaike-Cooke, Bryna Warshawsky, Kelsey Young

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
NL: [redacted]
PE:
NS:
ON:
MB:
SK:
AB:
YK:
NT:
NU:

Invited Participants:

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National Defence: Marie-Christine LaMontagne
Correctional Service Canada: Jennifer Morse

VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committees and reminded members that Janssen will be coming to present to the committee on April 29, 2021, and that VSWG members have been invited. Members were also reminded to submit any feedback on the ACCA proposal to the CIC or VVWG Secretariats by end of day April 30, 2021. Members were also advised that starting the week of May 3, 2021, the committee will shift to the monthly rotating co-chair model and NL will be the PT co-chair for the month of May 2021. Erin (CIC Federal Co-Chair) thanked members for sending in their responses to the question regarding PT measures for COVID-19 hot spots.

2. Update on Procurement of 1mL Syringes

Heidi Rodger (PHAC) informed the committees that the next [redacted] will now be arriving on May 2, 2021. A shipment of [redacted] which was anticipated to arrive at a later date, will now be arriving earlier, on April 30, 2021. There is no flight date yet for [redacted] but PHAC is expecting them to be ready to ship around April 30, 2021. Heidi (PHAC) confirmed that there have been around [redacted] syringes distributed to PTs to date, with more being shipped out this week. It was noted that PHAC has been in contact with most PTs and it appears that they are doing well with stock at this time. Heidi (PHAC) encouraged members to contact her via email should PTs have any specific questions to ask.

BC asked if any information could be provided regarding what's happened to retrieval rates for Pfizer 6 dose vials. BC has heard anecdotally that immunizers are experiencing issues withdrawing six doses after initial success. Heidi (PHAC) could not speak to this and asked if the NOC could comment on this. Erin Henry (CIC Federal Co-Chair) advised that a follow-up survey could be done to ensure that PTs are still getting six doses if the NOC is unable to provide an update on this.

3. COVID-19 Vaccine Logistics Update

Simon Côté (PHAC) provided the weekly COVID-19 vaccine logistics update, noting that over 14.4M doses of COVID-19 vaccine have been distributed to FPTs. Members were advised that Pfizer deliveries for the week of April 26, 2021 started on Monday and that most will be completed by April 28, 2021, with a small portion arriving at some VDS' on April 30, 2021. Moderna deliveries for the week of April 26, 2021 are scheduled for April 29 and 30, 2021. Simon (PHAC) noted that there have been no changes to the Pfizer numbers for future shipments, and that allocation tables have been shared with FPTs for these shipments. The allocation tables for the Moderna shipment for the week of May 10, 2021, were sent out to PTs with due dates for requests for orders earlier this morning. Quantities, dates, and allocation tables for the remainder of May 2021 for Moderna are still to be confirmed. Members were advised that the Janssen product is expected to arrive in Canada in the coming days however PHAC still needs to determine the delivery dates in order to confirm the allocation tables before they are issued to FPTs. PHAC is aiming to circulate the allocation tables for Janssen by the end of the week of April 26, 2021, with the distribution of those doses either the week of May 3, 2021 or May 10, 2021.

MB asked if the allocation tables can be provided to FPTs before delivery dates are determined for planning purposes. Jacqueline Kosche (PHAC) replied that there will be a conversation at the Special Advisory Committee (SAC) meeting following this meeting to discuss potential uses for the vaccine in

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terms of which populations PTs are considering for the use of this vaccine, recognizing that the NACI statement is still pending and the product is authorized by Health Canada for use in individuals over the age of 18 years.

AB asked if the discussions at SAC will have an impact on how the Janssen doses are allocated. Jacqueline (PHAC) replied that at this time, PHAC is anticipating normal allocation, but part of the discussion at SAC will be whether or not PTs are going to use Janssen in their programs. If there are jurisdictions that are not using these vaccines, then those doses can be redistributed as required.

AB asked if there is information on the Janssen packaging and expiry labelling. Erin (CIC Federal Co-Chair) replied that Janssen will be coming to present to CIC/VSWG on April 29, 2021, and will go through all of that information then. Janssen is expected to provide their meeting materials to the CIC Secretariat by late tomorrow afternoon, so the CIC Secretariat will advise members once they have been posted in advance of the meeting.

4. Management of Vaccination Errors

Bryna Warshawsky (PHAC) provided an overview of a draft Management of Vaccination Errors guidance document which is intended to assist HCPs by providing an approach to managing COVID-19 vaccines that are administered in a manner that differs from the recommendations of the manufacturer and/or NACI. Bryna (PHAC) sought feedback from members on the document, specifically the proposed guidance for site/route, intervals between doses, dosage, and diluent. Bryna (PHAC) noted that PHAC did reach out to Pfizer and Moderna on some of the questions and that Pfizer has generally advised to following CDC's guidance, while Modena has committed to getting back to PHAC with responses.

Following the meeting, the CIC Secretariat will send out an email seeking comments/feedback on the document and once those have been incorporated, the document will be presented to NACI.

BC asked if the document will be posted online or just distributed for use. Erin (CIC Federal Co-Chair) replied that PHAC could likely do both, and noted it may be good to include it as part of the HCP toolkit. Bryna (PHAC) advised caution regarding posting the document online as it may be misconstrued as indicating vacation errors are acceptable. BC suggested that in addition to reviewing the document, PTs should consider whether they intend to post it on their provincial/territorial website. Bryna (PHAC) added that PHAC will see whether NACI wants to take on more guidance related to errors in the administration section of the Canadian Immunization Guide. BC noted that the guidance could also be added as an appendix of NACI's COVID-19 vaccine statement.

5. Vaccine Safety Update

Natalia Abraham (PHAC) provided an update on Thrombocytopenia Thrombosis Syndrome (TTS) and Myocarditis in CAEFISS. Members were informed that as of April 26, 2021, there are a total of six TTS cases in Canada and an additional four cases are under review and investigation by PTs right now.

The Brighton Collaboration case definition for TTS was presented to VVWG late the week of April 19, 2021, and PHAC is currently receiving input from VVWG members on a set of questions regarding how to apply the Brighton Collaboration case definition in Canada, and with regards to the anti PF4 status and proposed sub-types within the definition (e.g. positive, negative, unknown status).

Natalia (PHAC) informed members that following reports from Israel of myocarditis following vaccination with Pfizer, PHAC has identified six cases of myocarditis following Pfizer administration as of April 26, 2021, and high-level details of the cases were shared.

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BC asked if Israel is the only place that this is being seen. Susanna Ogunnaike-Cooke (PHAC) replied that the Department of Defence in the U.S. is aware of 14 cases amongst defence personnel and they're currently looking into these cases.

BC asked when PHAC expects to distribute the finalized case definition for TTS. Susanna (PHAC) replied that at this point, PHAC really wants to get input from PTs on this joint recommendation, then it will go to SAC for their official concurrence. PHAC is hoping to have SAC endorsement by early the week of May 3, 2021.

PHO asked what the reporting rate is for TTS in terms of per doses distributed or administered. Natalia (PHAC) replied that the vaccine safety team at PHAC receives weekly updates on total doses administered and that the denominator is updated once a week. Based on earlier calculations that were done, the rate was between 1 to 2 cases per 100,000. Natalia (PHAC) noted that the rate is a bit of a moving target as it is highly dependent on the amount of vaccines that were administered at the time that these cases arose so PHAC will inflate the estimate if they take a snapshot of doses administered. Bryna Warshawsky (PHAC) added that the one thing we know for sure is the number of COVISHIELD doses that are in the country (500,000 doses). Five of the six cases of TTS have been confirmed to have occurred following vaccination with COVISHIELD, therefore the minimum TTS rate is 1 in 100,000, but this number could be higher if the other reported cases were also following vaccination with COVISHIELD.

6. NACI Update on AstraZeneca

Kelsey Young (NACI Secretariat) provided an update on NACI's recommendations for the use of AstraZeneca COVID-19 vaccine and the updated benefit risk assessment.

BC asked if any information could be shared with regards to NACI's approach to the Janssen COVID-19 vaccine. Kelsey (PHAC) replied that a very similar approach was used for Janssen and that NACI did discuss the recommendations yesterday and came to a conclusion, however, she was unable to speak to the statement as it was not approved yet. NACI is aiming to publish the statement on May 4, 2021.

BC asked if the guidance will be published before the vaccine is distributed to FPTs. Kelsey (PHAC) replied that to her understanding, the guidance will be released on the same day that PHAC is expecting to distribute the vaccine (May 3, 2021).

7. Roundtable

BC asked if further details could be provided [redacted] Jacqueline Kosche (PHAC) replied that she did not have additional information to provide but noted that PHAC is meeting [redacted] and she would ask for an update then bring it back to CIC on April 29, 2021.

Members were asked to comment on the following question:

- Which population(s) will your jurisdiction be targeting with the Janssen COVID-19 vaccine doses that will be coming next week?

Jacqueline (PHAC) noted that PHAC is interested in hearing what level of interest there is from PTs to offer this product as the allocation tables have not been drawn up yet.

AB asked if any other PTs are offering the Pfizer vaccine to 12-15 year olds with health conditions.

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YK – YK has not put in a request for Janssen.

NT – NT asked if this vaccine would be in addition to the vaccine that the territory has been allotted in Q2. NT noted that they have nothing intended right now, but added that they are potentially interested in receiving vaccine in Q3 and would want more information for Q2.

NU – As far as they are aware, NU is not requesting Janssen doses but NU committed to following up with colleagues to confirm.

NL – NL hasn't made any firm decision on how they will use Janssen – they're waiting to hear what's discussed at the SAC table. Some things that come to mind are using it for open calls, as their vaccination appointments are currently booked electronically, or using it for a targeted group, but nothing is definitive yet.

PE – Same as NL, PE hasn't made any firm decision on who they will be using the Janssen product for as of yet.

NB – NB is planning to use Janssen for all Acute Level of Care (ALC) patients and hospitalized patients who are in the hospital for longer stays, then would move to the age cohort approach (likely adults aged 50+).

NS – NS hasn't landed on anything firm yet but discussions are ongoing regarding the use of this product in correctional facilities, especially for the remand population.

QC – QC is awaiting an opinion from their expert committee. Some questions were raised including if there is an age limit – if there is no age limit, QC would like to favour usage of this vaccine for mobile populations that might have issues accessing a second dose. The other question raised was whether this is a vaccine that can be used in one region with a predominance of South African variant transmission that is a bit behind on vaccination coverage. QC will see what responses come back and can provide more information next week.

ON – Decision is still pending.

MB – Decision is still pending – MB is waiting for NACI to finalize its recommendations and possibly even discussions at SAC to help inform their decision on who to use this vaccine for. MB does not believe they are vaccinating 12-15 year olds with health conditions with the Pfizer vaccine.

SK – Decision has not been made – being discussed today at clinical expert group and it is expected that a recommendation will come forward but SK had no firm timeline on that.

AB – [redacted]

BC – [redacted] indicated interest in using this vaccine in mobile populations where it might be difficult for individuals to receive their second dose (e.g. rotational workers, workers in mines, forest firefighters, cross-border trucking, etc.). Another consideration is that these professions are largely male-dominated (given propensity for females in U.S. data).

MB asked if there has been any consideration of a second dose after a single Janssen dose or consideration of one dose of any of the COVID-19 vaccines to be equivalent regardless of what the

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Product Monograph states given what is known about efficacy. MB added that the efficacy data [redacted] and was curious to know if this has been discussed at any other PT medical and scientific advisory groups. Kelsey Young (PHAC) commented that NACI is aware that [redacted]

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CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE
April 6, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE:
NS:
NB:
QC:
ON:
MB:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Mark Sagan
HC/BRDD: Robert Pless
VVWG: [redacted]
CIRC: Nicolas Gilbert, [redacted]
PHAC: Robert Spencer, Simon Côté, Natalia Abraham

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
NL: [redacted]
PE:
NS:
MB:
SK:
AB:
YK:
NT:
NU:

Invited Participants:
PSPC: Marie-Ève Benoit
National Defence: Marie-Christine LaMontagne

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Correctional Service Canada: Jennifer Morse

VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committees and reminded members to complete the short mid-year check-in survey for the committee by end of day today, and noted that the CIC Secretariat appreciates any feedback that PTs can provide as it will help to ensure that the committee is meeting their needs. Members were also reminded to submit responses to the questions regarding COVID-19 immunization records to the CIC Secretariat by end of day April 6, 2021.

2. Update on Procurement of 1mL Syringes

Robert Spencer (PHAC) informed the committees that, to date, approximately [redacted] 1 mL LDV syringes have been allocated and shipped to provinces. Given the frequency of [redacted] receipts, and the consolidation of NESS warehouses, individual shipments received within a given week will no longer be cleared, allocated and distributed individually, but rather consolidated for efficiencies in warehousing and logistics operations, and then distributed to provinces. PHAC continues to recommend the optimal use of the [redacted] 1mL LDV syringe with the Pfizer vaccine.

Approximately [redacted] syringes are due to arrive by air charter in Calgary on April 6, 2021 and are expected to be distributed later this week. [redacted] more units are expected on April 9, 2021 in [redacted] for delivery to the [redacted] during April 10 and 11, 2021, and will be distributed to provinces over the following days. A further [redacted] syringes are expected on two charter flights to [redacted] on April 13, 2021, for delivery to the [redacted] during April 14 and 15, 2021, and distribution to provinces will occur in the days that follow. Approximately [redacted] more units are scheduled to follow between April 20, 2021 and the end of April 2021. As was noted last week, between the end of April 2021 and the first week of May 2021, PHAC expects to have received and distributed approximately [redacted]

3. COVID-19 Vaccine Logistics Update

Simon Côté (PHAC) provided the weekly COVID-19 vaccine logistics update, noting that over 10M doses of COVID-19 vaccine have been distributed to FPTs. Members were advised that last week's deliveries, including deliveries that were made on the Saturday of the long weekend, went very well. Most of the AstraZeneca U.S. supply was delivered to FPTs on April 1, 2021, as Health Canada provided approval earlier than anticipated. Moderna deliveries for the week of March 29, 2021 are almost done with the exception of a few remaining places that asked for later shipments or were on a two-day schedule. Pfizer deliveries for the week of April 5, 2021 are expected to be completed by April 7, 2021. PHAC met with Moderna on the morning of April 6, 2021 to discuss the schedule for the week of April 12, 2021 – the current plan is that the product would be released on April 12, 2021 so that deliveries could start on April 14, 2021. If this schedule changes, PHAC will notify FPTs.

The AstraZeneca doses coming from the COVAX facility are expected to arrive in Canada on April 8, 2021, with deliveries planned to start on April 9, 2021. This change in date is due to a release delay from the manufacturer. PHAC will ship the doses out earlier if possible.

PHAC is still expecting 1.5M doses of COVISHIELD in Q2 but the quantities, timelines, and allocation tables are still to be confirmed. PHAC is expecting to receive Janssen doses at the end of April 2021, however, the quantities, timelines, and allocation tables are still to be confirmed.

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MB commented that the changing delivery dates for Moderna shipments will have massive impacts on vaccination appointments. Milan Patel (PHAC) replied that [redacted] PHAC is expecting to receive the numbers for the Moderna shipments for May 2021 later this week and hopes to work in a buffer so that delays are accounted for in planning.

NS asked if the AstraZeneca product coming from the COVAX facility is manufactured in Europe or South Korea. Milan (PHAC) replied that the product is coming from Europe, however, it was manufactured in South Korea.

Heather Deehan (PHAC) informed members that on April 1, 2021, Janssen indicated to PHAC that Canada should expect a vaccine delivery the week of April 26, 2021, therefore, PHAC is tracking deliveries for the Janssen vaccine starting the first week of May 2021. PHAC is expecting to confirm the quantity of doses with Janssen either April 6 or 7, 2021, and will update PTs once that information is available.

MB asked if the India export ban will affect the COVISHIELD deliveries that are expected in April 2021. Heather (PHAC) replied that, in all likelihood, deliveries will be affected and noted that PHAC is waiting for written confirmation from the Serum Institute of India (SII) before informing FPTs. PHAC continues to track this very closely and SII has not confirmed any delivery dates as of yet.

A question was raised regarding the delivery schedule for Janssen. Heather (PHAC) replied that by late Q2, Canada should be receiving millions of Janssen doses. Heather (PHAC) noted that there have been production challenges in the U.S. that have affected Janssen's commitment and quantities for U.S. markets, and that members will receive a fulsome update from Janssen when they present to CIC/VSWG on April 20, 2021.

BC asked when PTs can expect the Moderna allocations following the week of May 19, 2021. Heather (PHAC) replied that PHAC was originally tracking for deliveries every two weeks, however, given the challenges that Moderna is facing with regards to managing production, quality, release, and EU importation processes, PHAC is looking to move to a weekly shipment schedule so that Canada has an ongoing rolling supply of Moderna doses. PHAC has asked Moderna to look at a weekly shipment schedule to keep supply rolling and to see if the current delivery schedule can be improved. Canada is expecting to receive 4M Moderna doses in May 2021, and PHAC will be discussing the delivery schedule with Moderna on April 8, 2021.

QC asked if there is any news on Moderna with regards to a possible switch to 11 or 15 doses per vial. Heather (PHAC) replied that PHAC is currently sourcing supply from Europe, and that there is no immediate move to have 11 or 15 doses per vial from the European facility right now. However, PHAC continues to track this closely to ensure long lead time should there be any changes. PHAC has a discussion scheduled with Moderna on April 7, 2021, and will keep members updated as required.

4.0 Update on CAEFISS Thrombosis/Thrombocytopenia Cases

Natalia Abraham (PHAC) provided an update on cases of thromboses and thrombocytopenia that have been reported to CAEFISS and the Canada Vigilance Database for COVID-19 vaccines. Natalia (PHAC) advised members that the EMA was expecting to release an update today, however, their meeting was cancelled and rescheduled for next week.

Erin Henry (CIC Federal Co-Chair) asked if PHAC has a communications SOP for the first case in Canada. Susanna Ogunnaike-Cooke (PHAC) replied that PHAC will be drafting communications pieces that will be shared with communications colleagues in PTs once available. Erin (CIC Federal Co-Chair)

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noted that once media lines are approved, it would be helpful to share them with members through the CIC Secretariat as well.

MB asked if there is any U.S. data on the Janssen product around CVST or thrombotic events outside of the clinical trials. Bryna Warshawsky (PHAC) noted that there is an informal rumour regarding a case that is under investigation but did not have any further details. Bryna (PHAC) asked if someone would be able to reach out to PHAC's CDC counterparts for more information. Robert Pless (Health Canada) noted that attempts were made last week to reach out to CDC but they still hadn't heard back and he committed to following up with Matthew Tunis (NACI Secretariat) for an update. Erin (CIC Federal Co-Chair) added that at the NACI meeting last week, the U.S. colleague did not have any information at that point but she did note that the U.S. had distributed around 3M doses of Janssen and it was something they were looking for.

BC asked if any information could be provided with regards to the FDA's plans to review the AstraZeneca vaccine. Robert (Health Canada) replied that he is not sure [redacted] Heather Deehan (PHAC) noted that the indication today is that [redacted]

5.0 Roundtable

Members were asked to comment on the following questions:

Q1 – Which populations is your jurisdiction targeting for the AstraZeneca and COVISHIELD COVID-19 vaccines?

Q2 – Has your jurisdiction identified any specific challenges with regards to distinguishing the AstraZeneca and COVISHIELD products in health data systems (e.g. immunization registries)?

MB asked, with regards to the coverage data that is posted online, if PTs are reporting actual doses administered or just estimates based on appointments and doses that are distributed. Nicolas Gilbert (CIRC Federal Co-Chair) replied that PTs are asked to report on actual doses administered, and it is expected that PTs report based on their immunization registries.

BC asked if the vaccine safety surveillance data sharing proposal, which was presented to SAC on April 1, 2021, and recommends the public posting of CAEFISS data received from PTs, could be discussed today or at a future meeting. BC noted that this item was added to CIC's work plan following discussions at CIDSC in 2017. Susanna Ogunnaike-Cooke (PHAC) informed members that under normal circumstances, the proposal would have come through VVWG and CIC, however, PHAC was asked to accelerate this proposal and go straight to SAC. The presentation was made to SAC on April 1, 2021, and it was proposed that 11 select variables be available online so that they can be accessed by Health Canada, manufacturers, and internationally. The feedback received from members was that SAC is in favour of sharing this information for pharmacovigilance purposes, however, SAC was not in favour of posting this information online. As a result, PHAC will need to do more work to determine possible proposals to make this information available without posting it online. SAC members have until April 8, 2021 to provide written feedback on the proposal.

BC asked when this item will be brought back to SAC. Susanna (PHAC) replied that PHAC does not have a date to go back to SAC with a revised proposal at this time. BC asked if it would be possible for CIC to provide input on the proposal. Susanna (PHAC) replied yes and advised comments could be sent to the CIC Secretariat or via SAC members.

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BC replied as follows:

Q1 – BC is maintaining their decision to use AstraZeneca and COVISHIELD for 55-65 year olds and the communication in BC was that this was a temporary change and it will be revisited.

Q2 – BC has been having lots of challenges distinguishing the two products, including in their immunization registry. BC noted that now that their province has pharmacists immunizing and have access to these products because of their fridge stability, they discovered that pharmacies had not distinguished these products within their system. Another issue that was flagged was that the U.S. labelled product was presenting specific challenges with respect to tracking in pharmacies' systems, and BC is working to remedy this issue. Robert Pless (Health Canada) noted that the DINs for these products are distinct but there does seem to be some difficulty in tracking the products, and other countries are having some issues as well.

BC asked if the U.S. labelled product has a Canadian DIN. Heather (PHAC) replied that the DIN for doses coming from the COVAX facility as well as the AstraZeneca doses coming from the U.S. are the same, and that PHAC has been looking at the GTINs to help distinguish the two products within information systems. The DIN for the COVISHIELD doses from SII have a different DIN. Milan Patel (PHAC) added that it's reasonable that pharmacies are having difficulty distinguishing the products because the DINs aren't printed on the labels, however, if the lot number is identified, then through paperwork, PHAC can connect the lots to the right DINs. BC noted that their province has flagged that the lot number is critical and that pharmacists are currently logging the lot number into a text field and not a direct field in their information systems.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

SK replied as follows:

Q1 – SK is using the AstraZeneca COVID-19 vaccine in adults 55 years and older however it is contraindicated for individuals who have a history of HIT or a thrombosis event linked with anti-coagulants.

Q2 – SK was unable to comment but noted there could potentially be some issues distinguishing the products for the AstraZeneca products coming from the U.S. and the COVAX facility. These products are being used in public health-run clinics.

MB replied as follows:

Q1 – MB is using the AstraZeneca COVID-19 vaccine in adults aged 55-64 years with high risk medical conditions followed by adults aged 65 years and over. These products are being administered at pharmacies and medical clinics, and MB is looking at an expansion to homebound clients but this is still under discussion/planning.

Q2 – MB has identified the AstraZeneca and COVISHIELD COVID-19 vaccines as two separate products in their system, however, once a dose is administered, MB is unable to distinguish what

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vaccine an individual has received – only medical clinics would be able to distinguish the products based on the lot numbers.

ON replied as follows:

Q1 – ON is using the AstraZeneca COVID-19 vaccine for individuals 60 years and older through a pharmacy model, and there are also some select family physician offices offering the product in select public health units.

Q2 – ON is doing quite a bit of work in terms of preparing the two products as they make their way through the system including the immunization registry and [redacted] to be able to distinguish them.

QC replied as follows:

Q1 – Last week, QC made a decision to vaccinate individuals aged 55-79 years with the AstraZeneca and COVISHIELD COVID-19 vaccines, however, QC was more or less out of COVISHIELD doses at that time so they haven't administered vaccine to this group since the NACI statement was released. QC is planning on distributing these products to pharmacies as well as having separate clinics so it would be obvious for patients coming in that they've booked an AstraZeneca appointment which is a change in policy for QC as they were previously using an "all vaccine is a good vaccine" approach. QC is meeting this afternoon with senior management to finalize their plan.

Q2 – QC does not believe distinguishing the two products is an issue for their province – they distinguish vaccines in their immunization registry by lot number.

PE replied as follows:

Q1 – PE is using the AstraZeneca COVID-19 vaccine in individuals over 55 years of age and these will be administered in pharmacies.

Q2 – PE has yet to administer any of these doses yet as they are rolling out the vaccine this week, but they are able to identify between the two products in their system.

NS replied as follows:

Q1 – NS is using the AstraZeneca COVID-19 vaccine in individuals aged 55-64 years and these will be administered in pharmacies and physician offices.

Q2 – NS is not running into difficulties distinguishing the COVISHIELD and AstraZeneca COVID-19 vaccines.

NB replied as follows:

Q1 – NB is using the AstraZeneca and COVISHIELD COVID-19 vaccines in individuals over 55 years of age and they are being administered in RHA clinics and pharmacies.

Q2 – NB has added both products to their public health information system and they are two separate products in Panorama as well. NB is going back and forth with pharmacies because of the fact that the DIN is not on the U.S. labelled products.

NL replied as follows:

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Q1 – NL is using the AstraZeneca and COVISHIELD COVID-19 vaccines in individuals aged 55-64 years and they are being administered strictly through public health right now.

Q2 – NL's data management system has been distinguished for both products.

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Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE
February 25, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted] (BC)
NL: [redacted]
PE:
NS:
NB:
QC:
MB:
SK:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
ISC: Melanie Knight, Mark Sagan, Chantale Chisholm
HC/BRDD: Robert Pless
VWG: Amanada Shaw, [redacted]
CIRC: Nicolas Gilbert, Kari Bergstrom
PHAC: Robert Spencer, Simon Cote, Cole Petersen, Stephen Bent

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
NL: [redacted]
PE:
NB:
ON
MB
SK:
YK:
NT:
NU:

Invited Participants:
PSPC: Marie-Ève Benoit
National Defence: Julie Nadeau, Marie-Christine LaMontagne

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ATIA-16(2)(c)

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VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed members and reminded the committees that the French version of PHAC's webinar geared towards allied, new and returning healthcare providers who will be administering COVID-19 vaccines will be held on February 26, 2021 from 1:00 – 3:00 PM EST. Members were advised that PHAC will be hosting a webinar on COVID-19 vaccine planning for immunization clinics (including a Q&A session) on March 1, 2021 from 12:00 – 2:00 PM EST (English) and March 4, 2021 from 12:00 – 2:00 PM EST (French). Members were also reminded to submit any feedback on the draft *Interim National Storage, Handling, and Transportation Guidelines for Ultra-low Temperature and Frozen Temperature COVID-19 Vaccines* document to the CIC Secretariat by COB March 3, 2021.

2. Update on Procurement of 1mL Syringes

Robert Spencer (PHAC) provided an update on the procurement of 1mL syringes, noting that all allocations of the first and second shipments of syringes have been delivered to provinces. The third shipment of syringes has been cleared by the NESS and shipments have left the [redacted] (BC, AB, SK, MB, ON and ISC have confirmed receipt). The fourth shipment has arrived at the [redacted] and is currently being counted and receipted. Once intake, Quality Assurance, and Quality Control processes are completed and the product is cleared by the NESS, it will be distributed to provinces with 100% allocation. Robert (PHAC) informed members that provinces and ISC are encouraged to distribute the 1mL syringes to all vaccine administrators and that the priority for the LDS 1mL syringes remains on the Pfizer vaccine at this time.

NB commented that they do not have any 1mL syringes left in stock to distribute and that as a result, they will have to use 3mL syringes with the Pfizer 6 dose vials. Robert (PHAC) took note of this comment and committed to providing a response to the CIC Secretariat regarding the status of their allocation for the third shipment of 1mL syringes.

ON asked what the total volume was of the fourth shipment that came in. Simon Cote (PHAC) committed to following up with this number and advised that it would be included in the slide deck containing the NOC's common operating picture.

BC asked if all shipments contain Maverin syringes. Robert (PHAC) confirmed yes.

3. COVID-19 Vaccine Logistics Update

Simon Cote (PHAC) provided an update on COVID-19 vaccine logistics, noting that all Pfizer doses have been delivered for the week of February 22, 2021 and that Moderna still had 134,800 doses to deliver for the same week. Future shipment amounts for Pfizer and Moderna for the month of March 2021 were presented. Simon (PHAC) advised members that Pfizer confirmed their shipments for the start of Q2, with 768,690 doses being delivered the week of April 5, 2021, and 768,690 being delivered the week of April 12, 2021 (allocation tables will follow).

QC asked if a decision has been made with regards to allocation adjustments for Indigenous or elderly populations by PT. Erin (CIC Federal Co-Chair) replied that the Special Advisory Committee (SAC) is awaiting NACI's recommendations on the extended dose interval which was being discussed at NACI on February 25, 2021. Bryna Warshawsky (PHAC) added that if an extended dose interval approach is taken, then allocation will be on a per capita basis. QC asked if the timeline for the decision on allocations would follow the SAC meeting on February 28, 2021. Erin (CIC Federal Co-Chair) replied

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yes, as NACI is going to present their recommendations to SAC on February 28, 2021. Heather Deehan (PHAC) added that until such a time that there is any decision to change, PHAC will continue to use the methodology that it has been using to date to manage allocations. Cole Petersen (PHAC) noted that allocation tables for Q2 are currently with Major-General Dany Fortin for review and approval and that they are based on a per capita breakdown, but will be adjusted based on SAC's deliberations if required.

BC asked for clarification on why a potential dose deferral recommendation would change allocation formulas. Bryna (PHAC) replied that if the dose deferral goes into effect, there will be enough doses to vaccinate everyone in Q2 and so no adjustments will need to be made for priority populations.

4. COVID-19 Vaccination Coverage Update

Nicolas Gilbert (PHAC) provided a COVID-19 vaccination coverage update based on reports that were submitted by PTs on February 22, 2021. Members were advised that NU provided their denominators for HCWs and congregate living estimates so they are now counted in the national estimates. The number of doses administered from February 14-20, 2021 is the highest weekly number of vaccine doses administered to date. Nicolas (PHAC) noted that PHAC and CIRC have started to discuss coverage plans for Q2 based on NACI's recommendations, but are waiting for a decision from NACI and SAC with regards to the extended dose interval. Based on NACI's current recommendations, Nicolas (PHAC) advised members that it was likely not possible to provide coverage estimates for all target populations in Q2 due to fluid populations in settings like shelters.

Erin Henry (CIC Co-Chair) informed members that NACI met on February 24, 2021 and reviewed and discussed the recommendations for AstraZenenca's COVID-19 vaccine. Although a copy of the recommendations were already circulated to members, Erin (CIC Federal Co-Chair) advised that members would most likely receive an embargoed copy of the updated recommendations by March 1, 2021, and that the recommendations could be discussed in more detail at the next CIC/VSWG meeting.

5. COVID-19 Vaccine Safety Update

Amanda Shaw (VVWG Federal Co-Chair) informed members that 278 AEFIs have been reported since the last update, and that most continue to be female and in the 18-49 years old age group. Ten deaths were reported since the last update, none of which are causally linked to COVID-19 vaccination.

Amanda (VVWG Federal Co-Chair) noted that the total number and rate of COVID-19 vaccine adverse event reports per week up to and including February 19, 2021 will not be posted publicly this week as PHAC wants to ensure that the messaging for this data is appropriate. ON agreed that any messaging that can accompany the data from a vaccine hesitancy point of view is really important.

ON asked if investigations into the 10 deaths following vaccination were considered completed and not associated. Amanda (VVWG Federal Co-Chair) was unable to confirm how many of the 10 deaths were fully investigated and determined not causally associated.

Milan Patel (PHAC) informed members that AstraZeneca and Verity Pharmaceuticals Inc./Serum Institute of India's (SII's) COVID-19 vaccines are both currently under review at Health Canada and that a decision is imminent (coming in the next day or two). From an access perspective, Canada is trying to secure access to both vaccines as soon as possible and negotiations are underway and near completion, so Canada may receive some doses from India within the next few weeks. PHAC is unable to share exact quantities today because the contractual obligations are not fully signed off yet, but PHAC should be able to share this information with PTs early next week.

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Milan (PHAC) offered to share the link to the list of vaccines that are currently under review by Health Canada with members, and noted [redacted] however they will be assigned different DINs.

6. Summary of Best Practices and Key Considerations for FPTs

Cole Petersen (PHAC) provided a brief summary of the FPT bilateral engagements that were held in early February 2021 to discuss Phase 2 planning. Cole (PHAC) noted that the engagements provided an excellent opportunity for collaborative planning and understanding what stages FPTs are at with regards to Phase 2 planning. An executive summary, which summarizes the highlights from the 15 different engagements, was prepared for Major-General Dany Fortin and shared with members. Cole (PHAC) then provided an overview of the COVID-19 Vaccine Forecasting Dashboard which PHAC developed in partnership with Health Canada and Statistics Canada. The tool features supply, administration, and demand forecasting.

In terms of next steps, PHAC is trying to establish a 4-6 week window for vaccine shipments and the NOC is working on determining PT allocations for upcoming shipments for Phase 2. Cole (PHAC) also advised members that the Rehearsal of Concept (RoC) is scheduled for March 9, 2021, and will provide the opportunity for FPTs to speak directly to specific readiness aspects for Q2.

Erin Henry (CIC Co-Chairs) informed members that the NOC sent out a call-out looking for PTs to present at the RoC, and noted that 1 or 2 PTs have already come forward.

7. Vaccine Support Injury Program Update

Stephen Bent (PHAC) provided an update on the Vaccine Support Injury Program (VSIP), which was first presented to CIC/VSWG in December 2020. Stephen (PHAC) noted that significant progress has been made since the last update. As a first step, PHAC reached out to all PTs to confirm whether or not they would opt in to the national program. All PTs have agreed to fall within the pan-Canadian VSIP with the exception of QC. In early February 2021, PHAC launched a call for proposals for a third party administrator which closed on February 24, 2021. PHAC received a number of proposals and will be going through the review process over the next couple of weeks, and is hoping to select an administrator by mid-March 2021. The review panel will include reviewers outside of PHAC, and it was noted that PHAC's VP has also reached out to her counterparts that were identified as part of correspondence between Deputies to determine the interest of PTs to participate in the review process. PHAC's VP has also set up a table of contact points identified by PT Deputies so PHAC will continue to have PT engagement as it moves forward with the program. While the goal is to have the third party selected by mid-March 2021, the program will not be stood up until June 2021. Stephen (PHAC) noted that SAC members raised a comment around a communications plan and that PHAC is currently working on it and thinking through how it can articulate that a third party has been selected in addition to establishing a presence on the Government of Canada's website.

AB asked how this work will overlap with some of the work being done within the VVWG, and how the program will integrate with the PTs with respect to data submission. Stephen (PHAC) replied that PHAC will need to work through what data sharing and information the third party administrator can have access to and what it can share given privacy restrictions. Stephen (PHAC) noted that individuals who present themselves will work through a medical practitioner. In the context of causality and looking at vaccine safety, PHAC will need to determine where the third party administrator will sit.

8. Vaccine Effectiveness Data Presentations

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[redacted] provided a presentation on Surveillance-based effectiveness of a single dose of COVID-19 vaccine in HCWs and LTCF residents in Quebec, followed by [redacted] who provided a presentation on Surveillance-based assessment of the effectiveness of a single dose of COVID-19 vaccine in HCWs and LTCF residents in BC. QC's study used three methodologies: 1) screening method, HCW, 2) retrospective cohort: using vaccinated cohort only, and 3) retrospective cohort: using vaccinated and unvaccinated, HCW. BC's study did not include a retrospective cohort approach as they are currently in the process of establishing that study database.

MB asked if there was any sense of the proportion of cases that were variants of concern vs. the 'parent' strain. [redacted] (BC) replied that BC is sequencing viruses that they detect in BC and have that sequencing available upon request but they are also doing background routine sequencing to establish a baseline assessment of period prevalence in the population. [redacted] (BC) noted that overall it is still the dominant viruses causing illness, especially in LTCFs. [redacted] (QC) added that QC is now sequencing potential variants of concern and will be in a position to evaluate vaccine effectiveness of these vaccines if the incidence of these variants are high enough.

Erin Henry (CIC Federal Co-Chair) reminded members that the two-week surveillance period for the number of Pfizer-BioNTech vials that have less than six doses will start on March 1, 2021, and encouraged provinces that can participate to do so.

Next meeting: March 2, 2021

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CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE

May 11, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Althea House for Erin Henry
P/T Co-Chair: [redacted]
NL: [redacted]
PE:
NS:
NB:
QC:
ON:
MB:
AB:
BC:
YK:
NT:
NU:

Invited Participants:
PHO: [redacted]
ISC: Melanie Knight, Mark Sagan
BRDD/HC: Robert Pless
VWG: Amanda Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
National Defence: Marie-Christine LaMontagne
Correctional Services Canada: Jennifer Morse
PHAC: Sean McDonaugh, Susanna Ogunnaike-Cooke
Health Canada: Mary Morgan

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
P/T Co-Chair: [redacted]
NL:
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NT: [redacted]
NU: [redacted]

VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Althea House (a/CIC Federal Co-Chair) welcomed the committees and informed members that the CIC Secretariat circulated the revised Management of Vaccination Errors guidance document yesterday which includes changes based on feedback that was received from members, and that Bryna Warshawsky (PHAC) will be returning on May 13, 2021 to discuss this next version. Members were advised that the CIC Secretariat also circulated the Agency's Vaccine Info Bulletin last Friday, May 7, 2021, which includes a link to the updated version of the COVID-19 vaccination tool kit for health care providers. Althea House (a/CIC Federal Co-Chair) informed members that Health Canada continues to work with Janssen and the other regulatory authorities to review all available information, and that there is outstanding information expected to come from Janssen the week of May 10, 2021.

2. COVID-19 Vaccination of Foreign Nationals

Mary Morgan (Health Canada) provided an update on the process that Health Canada developed with PHAC, Global Affairs Canada (GAC), and Canada Border Services Agency (CBSA) to ensure that foreign missions and embassies in Canada can vaccinate their employees. Health Canada first looked at requests from countries who wanted to vaccinate employees with vaccines that have been authorized in Canada, then they looked at requests from countries (e.g. China, Russia, Turkey) who wanted to use vaccines that have not been approved in Canada and how their foreign nationals could be vaccinated ahead of when they would be eligible based on the province or territories' vaccine rollout plan. Mary (Health Canada) informed members that at a very high level, the process remains the same in terms of submitting a request. The process of bringing vaccine into the country is similar to how Canada manages teams that travel for sporting events and bring their own physicians and medicine for their players. The guidelines around maintaining the integrity of the product including packaging, transport, and temperature controls, etc. remain the same and whoever is administering the product must be authorized to do so. Risk communications to patients must also be done by HCPs. Where this process differs is that anyone who is a Canadian and is working at an embassy would not be eligible to receive vaccines that are not approved in Canada.

To date, Health Canada has not received any formal requests to import vaccine that has not been approved in Canada. The two requests that have been authorized thus far have been for vaccine that was already authorized in Canada.

[redacted]

BC asked that, in the event that Canada receives a request from another country to import vaccine that has not been approved in Canada, if jurisdictions would be notified. Mary (Health Canada) replied that [redacted] BC noted that PTs have made significant efforts to record all doses administered into immunization registries, and asked whether this would be an issue for these populations. Mary (Health Canada) replied that she would inquire with GAC and noted that these individuals are not planning to stay in Canada, so she was unsure what that would mean for their immunization records.

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3. COVID-19 Vaccine Logistics Update

Sean McDonaugh (PHAC) provided the weekly COVID-19 vaccine logistics updated, noting that over 20M doses have been distributed to FPTs. Pfizer deliveries for the week of May 10, 2021 are ongoing. Sean (PHAC) informed members that Pfizer has advised PHAC that they are prepared to deliver the doses originally slated for the week of May 24, 2021 on May 20 and 21, 2021, in advance of the May long weekend (as a result, there would be no Pfizer deliveries the week of May 24, 2021). Moderna doses will also be delivered the week of May 17, 2021, and the quantities, dates, and allocation tables for the rest of May and June 2021 are still to be confirmed. Delivery dates for Janssen are still to be confirmed, pending Health Canada's regulatory release of the product. PHAC is anticipating to receive 655,200 AstraZeneca doses from the COVAX facility the week of May 17, 2021, and the allocation tables will be sent to FPTs via the NOC once they have been approved. PHAC is still expecting 1.5M doses of AstraZeneca/COVISHIELD from the Serum Institute of India, however these doses remain on hold.

AB [redacted]

ISC asked, given the recent approval of Pfizer in 12-15 year olds, if any adjustments are being made for future allocation tables for the territories and for remote areas. Jacqueline Kosche (PHAC) replied that PHAC has been in discussions with some of the territories and is aware of ongoing discussions between some territories and provinces regarding exchanging Pfizer doses for Moderna doses, and PHAC is fully supportive of this. PHAC is planning to have conversations with each of the territories the week of May 17, 2021, to understand how many additional doses they require then PHAC will look at adjusting allocation tables based on those discussions.

Althea House (a/CIC Federal Co-Chair) asked for clarification that PHAC will be having bilateral meetings with the territories the week of May 17, 2021. Jacqueline (PHAC) confirmed that this was correct and noted that following the FPTII Summit on May 5, 2021, PHAC also committed to organizing another round of PT bilateral meetings the first week of June 2021 to identify any additional lessons learned and any additional support that PHAC can provide to PTs. Jacqueline (PHAC) added that the NOC is always available to have additional bilateral meetings if any PTs are interested.

QC asked if they should proceed to book appointments for the Moderna doses that are expected the week of May 24, 2021. Sean (PHAC) advised to wait until PHAC receives confirmation from Moderna on the doses for that week before scheduling appointments.

[redacted]

4. Vaccine Safety Update: TTS Case Definition and Weekly AEFI Cases

Susanna Ogunnaike-Cooke (PHAC) provided an update on the development of the TTS case definition, noting that it was presented to the Special Advisory Committee (SAC) at their meeting on May 6, 2021. There is concurrence on the case definition and PHAC is now working to put it into a Word document

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format so that it can be shared with partners and posted online. Susanna (PHAC) noted that there was lots of conversation amongst SAC members regarding communications, reporting from PTs, VITT and how it fits within the case definition, etc. In terms of how these cases will be reported in the surveillance context, PHAC is looking to expand on the bullet points that speak to TTS which are already included in the online report. PHAC will be working closely with VVWG members for implementation of this reporting to ensure that everyone is well-supported and aligned. Susanna (PHAC) also noted that there was a lot of discussion at SAC around whether or not the case definition for TTS would result in over reporting or ascertainment. Given the information that PHAC has seen to date, individuals developing TTS following vaccination is not a common event so it is not expected that PHAC will be receiving a flood of reports that would ascertain this phenomenon.

NB asked if TTS will be reported as a negative functional assay. Susanna (PHAC) replied that PHAC could add a bullet in the online report regarding the cases that were negative.

Susanna (PHAC) informed members that she would provide an update on TTS cases and rates in Canada at the CIC meeting of May 13, 2021.

BC asked a question regarding the diagram which suggests that if the screening assay is positive, it's considered a VITT. Susanna (PHAC) replied that when a screening assay is positive, they are sent to the McMaster lab for confirmatory testing. If a person only received a screening assay in a hospital and it was not forwarded on to the McMaster lab then it would be considered positive.

BC asked, if the scenario whereby the screening assay is positive and the functional assay is negative, is not included in the diagram because it hasn't occurred yet. Susanna (PHAC) replied yes and if that happened, PHAC would confer with McMaster.

5. Roundtable

Members were asked to comment on the following questions:

Q1 – Are all PTs adhering to the 'no concomitant administration of other vaccines' recommendation from NACI?

Q2 – Do PTs have any updates regarding their plans for pediatric COVID-19 vaccination?

Q3 – For individuals who received a first dose of AstraZeneca, is your jurisdiction considering providing an mRNA vaccine for the second dose?

BC replied as follows:

Q1 – BC continues to receive questions regarding no concomitant administration and no administration of any vaccine within 14 days of receiving a COVID-19 vaccine. BC's standard recommendation in the absence of data is not to prevent all indicated vaccines at the same visit. This issue is arising particularly because of planning for school-based immunization programs. BC noted that in the management of vaccine errors guidance document, the advice given is that if you administer a vaccine in short order or at the same time of a COVID-19 vaccine, that none of the doses should be repeated.

Q2 – BC had a discussion with their public health executive and Dr. Bonnie Henry has made commitments to move ahead with vaccinating individuals aged 12+. BC may not proceed with school-based clinics due to limited capacity in areas hardest hit with COVID-19. The first dose for this age group will likely be provided in mass clinics but the information will probably be provided via the school setting.

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Q3 – This has not been discussed as an active strategy in BC. BC noted that they are hearing of individuals who received a first dose of AstraZeneca and are wanting to receive a second dose of an alternate product, and that the messaging from [redacted] is that rates of TTS are lower with the second dose.

AB replied as follows:

Q1 – Similar to BC, [redacted]

Q2 – [redacted]

Q3 – [redacted]

SK replied as follows:

Q1 – Similar to AB, SK is looking for more guidance before they deviate from NACI's recommendations regarding intervals between COVID-19 and other vaccines.

Q2 – It was announced in SK that Pfizer will be offered to individuals aged 12-15 years, and that this age group will be added to the province's vaccination sequencing. SK will start vaccinating this age group once first doses have been provided to all adults, with the exception of critically vulnerable individuals in this age group who are currently eligible. SK is trying to incorporate Pfizer COVID-19 vaccination into their school immunization program and planning is underway. MB asked if SK will be providing first doses in mass clinics and second doses in schools for this age group. SK replied that their goal is to offer first doses in schools, but homeschooled children or those who would prefer to go to a mass clinic would be able to go to a mass clinic.

Q3 – SK has not made any decisions on offering mRNA vaccine as the second dose to individuals who received a first dose of AstraZeneca.

MB replied as follows:

Q1 – MB hasn't deviated from NACI's recommendations and is still following best practices around administration with other vaccines. MB has received questions around someone who received a Td vaccine less than 14 days before their COVID-19 vaccine.

Q2 – MB is looking to announce their adolescent vaccination program – they are currently focusing on individuals aged 18+ and will be announcing the program for 12-17 year olds in the coming days (this age group is not eligible yet).

Q3 – MB noted that they asked this question given they've heard that some PTs might be moving towards this approach.

ON replied as follows:

Q1 – ON is following NACI's recommendations and noted they are glad that NACI will be revisiting them before the fall/influenza season.

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Q2 – [redacted]. Priority populations will be receiving their second doses earlier now that vaccine supply is increasing.

Q3 – ON is considering offering mRNA vaccine as the second dose to individuals who received a first dose of AstraZeneca. ON noted that vaccine hesitancy is quite high for the AstraZeneca product and that their Minister of Health has publically signalled that ON is considering mixing COVID-19 vaccine brands for first and second doses.

QC replied as follows:

Q1 – QC is following NACI's recommendations but noted that one issue that keeps arising is regarding cancer patients who need to receive their COVID-19 vaccine but are also often booked for other vaccines prior to receiving immunosuppressive treatments. QC noted it is challenging to coordinate these vaccines given the 14 day period following COVID-19 vaccination for which NACI recommends not to administer any other vaccines. QC has received repeated requests from oncologists to change this 14 day period but QC noted that this has not been reviewed yet. The other issue that has been raised is around co-administration of vaccines for 12-17 year olds, as school immunization programs are hoping to have the opportunity to do catch-up clinics for grade nine students, especially in the regions hardest hit with COVID-19. The school immunization program has been reduced or cancelled across QC so they will be raising this question to their expert advisory committee in terms of if it would be possible to have co-administration of COVID-19 vaccines with Gardasil and other vaccines onsite at schools.

Q2 – QC noted that with regards to pediatrics, they share a lot of the same issues that have been raised by members and that given that staff have been redirected for case and contact management and other public health needs, and with the transportation limitations of Pfizer, it will not be realistic for their province to offer first doses in all of their schools. QC is working with their Minister of Education to see how they can use the school system as a lever and a collaborator to ensure that consent forms are received and that there's organized transportation to mass clinics. QC is also working to determine whether they will be offering vaccination sooner to those who are clinically extremely vulnerable in the younger age group. QC is not just looking at those attending school for the 12-17 year age group, but also those who are homeschooled, are working, or have been staying home for the past year due to the severity of an underlying condition.

Q3 – QC just received an opinion from their expert advisory committee on this topic and noted that a variety of recommendations were put forward including mixed schedules. This guidance is currently under review and no final decision from QC's authorities or announcements have been made yet but this might be coming later the week of May 10, 2021.

NB replied as follows:

Q1 – NB is waiting on NACI to review their recommendations and have not provided any other advice.

Q2 – As of May 10, 2021, NB rolled out their vaccination program to 12-15 year olds in First Nations communities and have started a process to support communities that are immunizing adolescents in their communities and off-reserve. NB is also offering vaccine to this age group for those with underlying medical conditions. NB started offering vaccine to individuals aged 40+ as of May 10, 2021. NB is still determining how it will roll out their vaccination program for 12-15 year olds in the general population,

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and noted that if they do opt in for a school program, they are unsure if they would have the capacity to provide immunizers.

Q3 – NB does not have any kind of directive or advice on this and would be looking to NACI for more information.

PE replied as follows:

Q1 – PE is adhering to NACI's recommendations and looks forward to newer recommendations for the fall.

Q2 – Discussions are ongoing regarding PE's plans for a pediatric immunization program, and PE noted that they are unsure if public health nursing will have the capacity to offer a school-based immunization program.

Q3 – Similar to NB, PE is awaiting a decision from NACI and noted that they are not sure if individuals who received a first dose of AstraZeneca will want a second dose.

NS replied as follows:

Q1 – NS is following NACI's recommendations and is very interested to learn what NACI will come back will in advance of influenza season.

Q2 – NS will be continuing with an age-based approach to COVID-19 vaccination, and is looking to have 12-15 year olds vaccinated by the end of June 2021. Schools are currently closed province-wide so NS suspects that these vaccines will be provided via mass immunization clinics and pharmacy and physician models.

Q3 – NS is receiving correspondence from individuals indicating that they do not want to receive their second dose of AstraZeneca. NS has started to have very preliminary conversations around this and is anxious to see what NACI will say in the coming weeks.

NL replied as follows:

Q1 – NL is following NACI's recommendations.

Q2 – NL is hoping to start providing COVID-19 vaccines to the 12-15 year old age group starting the week of May 17, 2021. NL is still determining what that roll-out will look like, and noted that some regions may be offering vaccine in schools and in mass immunization clinics.

Q3 – NL is waiting for NACI's recommendations but also noted that they are receiving calls from individuals who do not want to receive AstraZeneca for their second dose.

NU replied as follows:

Q1 – NU is following NACI's recommendations.

Q2 – NU is still in preliminary discussions and no firm decisions have been made on whether they will be using Pfizer for 12-15 year olds.

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Q3 – NU is following NACI's guidance and noted they have had some transient workers looking to receive their second dose in NU. NU has advised these individuals to receive their second dose when they return down south at the 4 month interval.

NT replied as follows:

Q1 – NT is following NACI's guidelines and is attempting not to vaccinate in the 14 day period following COVID-19 vaccination, but noted they've had two outbreaks of pertussis and rabies where they did have to vaccinate during this period because their vaccination teams were in the communities at the exact same time when there were exposure concerns.

Q2 – NT rolled out Pfizer vaccine to individuals aged 12-17 years in Yellowknife and in three surrounding communities having outbreaks on May 6, 2021. NT is hoping to reach street-involved youth and suspect to be out of vaccine by May 12, 2021, but will be receiving more vaccine the week of May 17, 2021 and will be rolling out their school-based program to all communities and hope to vaccinate this age group before school ends on June 11, 2021.

Q3 – NT is encouraging individuals to get their second dose in their home community unless they are not returning there.

YK replied as follows:

Q1 – YK is following NACI's guidance.

Q2 – YK is looking to vaccinate their pediatric population (12+) and is currently determining how they can trade some Moderna doses for Pfizer doses with provinces.

Q3 – YK has had some individuals from out of territory that received a first dose of AstraZeneca and since YK does not have that product and the individuals were moving to YK, they restarted the series with an mRNA vaccine (2 doses).

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Partenaires en santé publique

CANADIAN IMMUNIZATION COMMITTEE AND VACCINE SUPPLY WORKING GROUP JOINT TELECONFERENCE

May 4, 2021

- Record of Decisions -

CIC Members:
Federal Co-Chair: Erin Henry
P/T Co-Chair: [redacted]
PE: [redacted]
NS: [redacted]
NB: [redacted]
QC: [redacted]
ON: [redacted]
MB: [redacted]
AB: [redacted]
BC: [redacted]
YK: [redacted]
NT: [redacted]
NU: [redacted]

Invited Participants:
ISC: Montana Massicotte
VVWG: Amanda Shaw, [redacted]
CIRC: Nicolas Gilbert, [redacted]
PHAC: Simon Côté, Sean Meredith, Milan Patel, Susanna Ogunnaike-Cooke

CIC Secretariat:
Alison Hunt, Natalie Gravelle, Sylvie Deschambault

VSWG Members:
Federal Co-Chair: Alan Thom
NL: [redacted]
PE: [redacted]
ON: [redacted]
MB: [redacted]
SK: [redacted]
AB: [redacted]
BC: [redacted]
YK: [redacted]
NT: [redacted]
NU: [redacted]

Invited Participants:
PSPC: Frederic Hamann
National Defence: Julie Nadeau, Marie-Christine LaMontagne

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VSWG Secretariat:
Carolyn Lacaille

1. Member Welcome and Introductions

Erin Henry (CIC Federal Co-Chair) welcomed the committees and informed members that moving forward, meetings will be 90 minutes in length and that the 1mL syringe update and vaccine safety update will be provided secretarially unless an urgent item needs to be discussed. Members were reminded that the FPTII Summit is happening May 5, 2021 and that they are still accepting 3-5 bullet points on best practices and lessons learned, particularly from PTs that will not be presenting at the summit. Erin (CIC Federal Co-Chair) advised members that someone from the NACI Secretariat will be providing an overview of the Janssen update and discussing NACI's forward plan at the CIC meeting on May 6, 2021. Members were reminded to submit responses to the questions regarding use of the Pfizer vaccine in adolescents aged 12-15 years to the CIC Secretariat by NOON EST May 6, 2021.

2. COVID-19 Vaccine Logistics Update

Simon Côté (PHAC) provided the weekly COVID-19 vaccine logistics update, noting that over 16.9M doses of COVID-19 vaccine have been distributed to FPTs. Members were advised that Pfizer deliveries for the week of May 3, 2021 will be completed by May 5, 2021. The Moderna shipment for the week of May 10, 2021, is expected to arrive in Canada on May 5, 2021 followed by pick and pack at [redacted] and forward distribution to FPTs starting May 6, 2021. PHAC has received confirmation on the Moderna shipment for the week of May 24, 2021, and allocation tables will be issued within the next few days for requests for orders. With regards to the AstraZeneca doses coming from COVAX, Canada will be receiving 1.2M doses in Q2 which are expected to come in two shipments – more information will follow as soon as it becomes available. The quantities, dates, and allocation tables for the AstraZeneca/COVISHIELD doses coming from the Serum Institute of India are still to be confirmed – given the current situation in India, PHAC does not anticipate that those doses will arrive in Canada over the next while.

Jacqueline Kosche (PHAC) informed members that the next shipment for Moderna is tracking for pick-up on May 17, 2021 for distribution the week of May 24, 2021, and that allocation tables for this shipment will be sent to FPTs very soon. PHAC is also tracking the COVAX deliveries very closely and is anticipating the arrival of around 655,000 doses by mid-May 2021 and these doses will have an end of August 2021 expiry date so the shipment can be used for second doses.

QC asked if the AstraZeneca quantities include doses beyond providing second doses to those that have already received their first doses. Jacqueline (PHAC) replied that when Canada received the first shipment of AstraZeneca doses, it was anticipated that 1M doses then 500,000 doses would follow, however, the shipment of these doses was paused due to export restrictions put in place by the Indian government. Those quantities (1.5M) still remain from the initial contract with Verity Pharmaceuticals. QC replied that it seems that by the time these doses are received, every adult will have had the opportunity to book an appointment for an mRNA vaccine so they don't see much use for these doses as first doses, especially since PTs will be going into younger age groups. QC also noted that they are seeing a phenomenon with thrombosis, as some individuals who received a first dose of AstraZeneca or COVISHIELD want a mixed schedule. QC suggested that there needs to be a discussion regarding the need for AstraZeneca. Jacqueline (PHAC) replied that there are ongoing conversations regarding AstraZeneca doses, including a discussion at the Special Advisory Committee (SAC) meeting today regarding the amount of mRNA vaccine that Canada will be receiving over the next couple of months.

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4. Update on Distribution of Print Materials

Milan Patel (PHAC) provided an update on the distribution of print materials, noting that PHAC has heard from PTs that the print copies are not really needed and can sometimes be a hindrance to receive. As a result, the vaccine manufacturers have asked what is needed in order for them to meet the requirements of PTs without breaking the terms and conditions of their authorization. Milan (PHAC) presented the proposal which outlines a distribution scheme that may be adopted by sponsors for each COVID-19 vaccine shipment moving forward and noted that the vaccine manufacturers and Health Canada are in agreement with this proposal. All materials are also available electronically by scanning the QR code on the product or by visiting Health Canada's website. Milan (PHAC) asked members if they had any concerns with this proposal – no members raised any concerns. ISC commented that this proposal will meet their objectives and thanked Milan (PHAC) for this great work.

Sean Meredith (PHAC) informed members that the NOC has been receiving a few comments from PTs with respect to what to do when and if doses are valid if immunizers are able to withdraw 5 or 7 doses from Pfizer vials. Sean (PHAC) advised that professional judgment takes priority in these situations, however, as a general rule, in the absence of reason to the contrary, as long as the vaccine has been drawn up and diluted properly then the vaccine can be administered to clients. Sean (PHAC) then asked if any members could share experiences regarding inconsistences coming out of the NOC. MB commented that they raised a similar question during a roundtable a few weeks ago on whether PTs are administering all doses that are withdrawn from Pfizer vials (whether it be 4, 5, or 7 doses) and most if not all PTs indicated that they were administering whatever was being drawn up. BC commented that they sent this question in to Pfizer as they have been getting reports of the occasional 4 doses out of the vial despite claiming to be reconstituting with the appropriate amount of saline. BC is also trying to get an update on retrieval rates for 6 doses as they have been hearing of challenges after initial success at the beginning. BC noted that it seems that a message went out through their logistics team that if immunizers are only able to withdraw 4 doses then they should not be administering any of them. BC has a call with Pfizer this morning to discuss. It was noted that this issue could possibly be added to the Management of Inadvertent Errors guidance document that Bryna Warshawsky (PHAC) is working on.

4. Update on Thrombosis with Thrombocytopenia Syndrome (TTS) Following COVID-19 Vaccination

Susanna Ogunnaike-Cooke (PHAC) provided an update on the development of the TTS case definition and the cases/rates of TTS in Canada. Susanna (PHAC) noted that PHAC has been working with VWWG and CIC on the case definition (based on the definition that came out from the Brighton Collaboration and was later updated), and that next steps including taking the proposed definition to SAC on May 6, 2021 and seeking their approval. Susanna (PHAC) informed members that as of the night of May 2, 2021, there are 8 cases of TTS in Canada (6 following COVISHIELD and 2 following AstraZeneca), and high-level details of the cases were provided. There are an additional 6 suspected cases under investigation.

BC asked a question regarding the denominator for the COVISHIELD rate. Susanna (PHAC) replied that the denominator being used is 493K doses (which is the number of COVISHIELD doses that were administered in Canada).

BC asked a question regarding a discussion around rate calculations and whether suspect cases should be included. Susanna (PHAC) advised members that the current suspected cases hit a lot of the points that are included in the case definition and that in a lot of cases, PTs are awaiting the results from the PF4 testing. It was noted that if this phenomenon is triggered by the vaccine then there is no background rate.

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QC asked if the plan is to equip some hospitals aside from the laboratory in Hamilton to do confirmation testing. Susanna (PHAC) replied no, and added that there are a few things in the works including: 1) PHAC has reached out to the community of expert hematologists to ensure there are individuals identified in each PT that can be consulted and can link with McMaster if necessary, and 2) PHAC is creating some overall guidance for Canada which is similar to the guidance that was developed for Ontario and includes an algorithm to determine what's happening with the case and initial testing to detect antibodies (using ELISA which is done in hospitals) then subsequent to that, test samples could be sent to McMaster. PHAC is working with the university to increase their testing capacity.

5. PT COVID-19 Hot Spot Measures

Erin Henry (CIC Federal Co-Chair) provided an overview of responses that were received from PTs regarding measures that they have put in place to target COVID-19 hot spots or areas with high COVID-19 transmission. Several members provided updates/additional information as follows:

BC noted that some of their worker groups that were identified for immunization had also been based on the occurrence of outbreaks. Another feature is that all along, vaccine allocation in BC has not been per capita as high incidence areas received a greater allocation. In some cases, the entire community has been immunized such as Prince Rupert.

[redacted]

SK commented that drive through clinics are going well and noted that they are a second option in some communities if booked appointments are full or the wait to book an appointment via phone is long. SK has heard nothing but positive things with regards to the drive through clinics.

MB commented that the week of May 3, 2021 might be the last week for the hot spot measures as MB may start to open up eligibility by age increments. MB is planning to go down in five year increments, three times a week meaning that starting on May 5, 2021, they will be offering vaccine to all individuals aged 45+, then 40+ on May 7, 2021, and so on. MB should be able to offer vaccine to all individuals aged 18+ by the May long weekend.

[redacted]

QC commented that they are still awaiting evaluation results from the strategy that was used to vaccinate parents and teachers of certain schools and offered to share more details when they become available. QC opened up vaccine eligibility to the entire population the week of April 26, 2021, and the age stratification decreases every couple of days. As of May 14, 2021, all individuals aged 18+ will be eligible to get a vaccine. Outreach strategies will then be deployed depending on pockets of low uptake in various regions. QC is aiming for a universal vaccination strategy with some sub-strategies to address specific concerns. QC noted that one question that has been raised is that now there is a very stable situation in Montreal but where QC is seeing the highest incidence rates of COVID-19 is in more remote areas. Erin (CIC Federal Co-Chair) advised that the CIC Secretariat could add an item regarding how PTs are evaluating different strategies to the forward agenda.

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NS commented that their logistics team have advised them than an age-based approach seems to be the most appropriate approach for NS and that adults aged 50+ became eligible for mRNA vaccines the week of May 3, 2021 and that it would seem that the trend is that in the next few weeks, NS will expand eligibility by going down in five year increments. NS is therefore expecting to be able to offer vaccine to adults aged 45+ the week of May 10, 2021, and to adults aged 40+ the week of May 17, 2021.

PE commented that similar to NS, they are using an age-based approach and have added in a few frontline workers and private sector employees in those clinics as well. PE is also offering vaccine to individuals aged 16+ who have underlying conditions and their family members as well. PE is hoping to offer vaccine to all adults aged 40+ by the end of May/early June 2021 and then to all adults by the end of June 2021.

NB had no further comments.

NL commented that they introduced the vaccination of high-risk groups in their province the week of May 3, 2021. NL continues to focus on an age-based approach and opened eligibility up to adults aged 60+ and pregnant women the week of May 3, 2021. NL anticipates going down by five year increments in the future and is also hoping to open eligibility to everyone by end of June 2021.

NU commented that they had created preliminary plans for a ring vaccination strategy but have not implemented it as of yet. NU noted that they are lucky that most of their communities have had mass immunization clinics and that their coverage is very good. NU does have specific public health orders in place in communities where there is COVID-19 transmission.

NT commented that they do have a hot spot now and just recently closed their schools in Yellowknife nd in two surrounding communities. The hot spot is in younger age groups and NT has also closed recreational facilities and instituted mandatory masking. In addition, NT has negotiated with two other PTs to receive some Pfizer doses to be able to vaccinate 16 and 17 year olds in Yellowknife. Erin (CIC Federal Co-Chair) asked if NT will be exchanging Moderna doses for the Pfizer doses they are receiving with the two PTs and NT confirmed that this was correct.

YK commented that one of their mine sites on the border of YK was becoming a hot spot so the territory provided support by rolling out vaccine at their sites and are just finishing up second doses now.

6. Roundtable

Members were asked to comment on the following questions:

Q1 – Which date did your jurisdiction start administering COVISHIELD and AstraZeneca COVID-19 vaccines?

Q2 – For jurisdictions that are using wait lists for leftover vaccine doses at the end of a clinic:

- Which individuals are being put on these lists?
- How are the lists generated?

Q3 – As was reported in the media today, Newfoundland and Labrador is the first province that has included seafarers in its plans to vaccinate rotational workers. Are any other provinces planning on including seafarers in their COVID-19 vaccination plans?

YK replied as follows:

Q1 – Question not applicable to YK.

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Q2 – YK was initially using wait lists due to limited vaccine supply. In the very beginning (January-February 2021), YK used internal lists of HCW staff. In February 2021, if there was one person left to vaccinate at the end of a clinic, YK would put that person on a wait list for the following day and try to collect enough (10) people for the next day to avoid wasting any doses from the vial. YK has wasted a total of 170 doses to date but has gained 800 doses due to the ability to withdraw 11 doses from some vials.

Q3 – YK has not discussed including seafarers as part of their COVID-19 vaccination plan.

NT replied as follows:

Q1 – Question not applicable to NT.

Q2 – Similar to the YK, throughout their rollout, NT tended to put people that were in the next category (e.g. age group, medical condition, or essential worker) on a wait list. As NT moves forward with their COVID-19 vaccine rollout, it is a bit of a struggle to find arms for doses at the end of the day. Some teams are proposing to add people that are currently in isolation centres that have returned from travel outside of the NT, and that nurses could arrange for these individuals to come into the clinic at the end of the day and additional precautions would be used. NT is also looking at doing dial-a-dose where nurses could deliver vaccines to people who have mobility issues or are unable to get to clinics at the end of the day. To date, NT has only wasted 31 doses out of 48,000.

Q3 – NT has not considered seafarers as part of their COVID-19 vaccination plan but noted that they are vaccinating anyone who is a rotational or transient worker and seafarers would fall within those groups.

NU replied as follows:

Q1 – Question not applicable to NU.

Q2 – Similar to the other territories, NU was initially creating wait lists when vaccine supply was lower. Since then, NU has been creating a running list of individuals who would like to be immunized and once they have close to 10 people, NU will open a vial and run a small clinic.

Q3 – NU has not specifically discussed the inclusion of seafarers in their COVID-19 vaccination plan but they are vaccinating transient workers so they believe that seafarers would be eligible depending on the logistics of actually vaccinating them.

BC replied as follows:

Q1 – BC was unable to comment.

Q2 – BC committed to providing a response to the CIC Secretariat via email but noted that they have heard that sometimes individuals that are in proximity of those eligible to receive the vaccine would be invited to receive a vaccine if there were any leftover after a clinic (e.g. acute care workers when LTC healthcare workers were being immunized). BC added that there has been a lot of sensitivity around people who are not in an eligible group being invited to receive a dose at the end of the day.

Q3 – BC asked if the definition for seafarer could be provided. Erin Henry (CIC Federal Co-Chair) replied that a seafarer would include workers on container ships and noted that some of the issues is that this group or workers are often in a bubble on their ship and are not allowed to leave the ship, so PHAC is interested in the creative ways that some regions might be immunizing these workers, particularly

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provinces that have ports. BC asked if this would require someone going onto the ship to vaccinate the individuals. Erin (CIC Federal Co-Chair) confirmed yes. BC noted that they haven't heard of this happening at this time but that there has been lots of discussion about prioritizing the Vancouver Coast Guard.

BC asked if an update could be provided regarding the embassy discussion that CIC had a while back, especially with regards to individuals who have been vaccinated with vaccines that have not been approved in Canada. Erin (CIC Federal Co-Chair) replied that she will ask Health Canada to come back to CIC to provide an update as they have been continuing to work on that file.

AB replied as follows:

Q1 – [redacted]

Q2 – [redacted]

Q3 – Question not applicable to AB.

SK replied as follows:

Q1 – SK started administering COVISHIELD on March 14, 2021.

Q2 – Wait lists are generally created at the local level in SK and would be based on current eligibility (e.g. age or other criteria).

Q3 – Question not applicable to SK.

MB replied as follows:

Q1 – MB started administering COVISHIELD on March 11, 2021.

Q2 – MB noted that they asked this question.

Q3 – Question not applicable to MB except for possibly the Port of Churchill but MB has not heard anything about it.

ON replied as follows:

Q1 – ON [redacted] AstraZeneca in early April 2021.

Q2 – Wait lists are done at clinics at the local level in ON based on eligibility criteria.

Q3 – One approach that ON is using in Toronto is hosting a foreign transient workers vaccination clinic at the Toronto Pearson Airport.

QC replied as follows:

Q1 – QC started administering COVISHIELD on March 10, 2021.

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Q2 – QC commented that there have been different approaches to wait lists in the past few months – there was a wait list that HCWs that had not previously been vaccinated or had an appointment further in the future could put their names on to be called at the last minute to get a vaccine. There were also wait lists for other staff in vaccine clinic settings (e.g. security guards, administrative employees). QC has now opened up vaccine appointments for the general public so they don't anticipate that they'll have as many unused doses at the end of the day as in previous months but they also acknowledged that they are aware that there are some groups in the population that will not response well to the appointment-based system and that a walk-in setup will be needed so that is also something under consideration in their province.

Q3 – Given that QC is opening up COVID-19 vaccinations to the general population and will be able to offer vaccines to all individuals over the age of 18 by May 14, 2021, seafarers could make a vaccine appointment if they fall within an eligible age group. It is not mandatory for individuals to have a health card to book a COVID-19 vaccination appointment in QC, therefore anyone who is in the province can book an appointment.

NB replied as follows:

Q1 – NB starting administering COVISHIELD on March 23, 2021.

Q2 – NB has a wait list guideline on their website and noted that some of their regions have posted leftover vaccine availability on FaceBook. Pharmacies and regional health authorities have also been creating wait lists so that they can call someone if an individual does not show up for their appointment.

Q3 – NB does have seafarers but was unable to confirm if this had been discussed – they have asked their colleagues and are awaiting a response.

NS replied as follows:

Q1 – NS started administering COVISHIELD on March 20, 2021.

Q2 – Wait lists in NS are dependent on the provider – pharmacies can use their own clients and residents need to be available on short notice. In the initial phases, pharmacies included their own immunizers on their wait lists. When vaccination appointments were cancelled, some pharmacists made the decision to focus on wastage concerns and offered vaccine to individuals that were not in eligible criteria. NS also has pharmacies that have been able to consistent get extra doses from vials so they will book extra appointments in advance. It was noticed that wait lists can drive calls to the pharmacies which impacts their business. Physician clinics don't have formal wait lists but they are finding that AstraZeneca vials are yielding an extra 1-2 doses so they have wait lists for patients that can attend the clinic on short notice at the end of the day to use up any punctured vials. NS does not think there are wait lists for public health unit mass vaccination clinics.

Q3 – At this point NS is primarily using an age-based approach and is not considering the prioritization of seafarers.

PE replied as follows:

Q1 – PE started administering COVISHIELD on March 11, 2021, and AstraZeneca the first week of April 2021.

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Q2 – PE's wait lists are generated by public health nursing and they have specific criteria – either people travelling for compassionate reasons or out of province travel for surgery, or those who are eligible like HCPs. The wait lists are for first doses only. The lists are generated through phone calls to public health nursing and at their CPHO office.

Q3 – PE hasn't really discussed seafarers and noted that anyone entering their province has to isolate for a period of 14 days, so PE wouldn't be vaccinating these individuals in a clinic until their isolation period is up.

NL replied as follows:

Q1 – NL started administering COVISHIELD on March 11, 2021, and AstraZeneca the first week of April 2021.

Q2 – NL's wait lists include individuals in priority groups, are generated in the clinic, and are overseen by support staff. NL has discussed the possibility of when their province can utilize wait lists for second doses for HCWs but have held off on that decision and they are now focusing on getting everyone their first dose first.

Erin (CIC Federal Co-Chair) reminded members that starting the week of May 10, 2021, the CIC Secretariat will strive to shorten meetings to 90 minutes. Erin (CIC Federal Co-Chair) also committed to reaching out to Health Canada to see if they can provide an update on the Janssen product at the next meeting.

Next meeting: May 11, 2021

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

May 5, 2021 | 1:00pm-3:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Bailey Beaudoin, Yung-En Chung, Kelly Farrah, Veronica Ferrante, Nicole Forbes, Allison Friedman, Anabel Gil, Renee Goddard, Christina Jensen, Ramya Krishnan, Nima Mohamed, Stephie Pierre, Kaeli Ramotar, Natalie St. Pierre, Angela Sinilaite, Rob Stirling, Chantale Tremblay, Matthew Tunis, Man Wah Yeung, Eva Wong, Min Xi, Raphael Ximenes, Kelsey Young, Joseline Zafack (25)
	PHAC & HC Participants	Natalia Abraham, Deborah Danoff, Kimberley Hutchings, Su Hyun Lim, Marina Salvadori, Amanda Shaw(6)
	NACI Members	[redacted]
	HCID Working Group Members	[redacted]
	[redacted] **Participants**	[redacted]
Total in Attendance	57	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests

WG Chair welcomed working group members, Pfizer participants, PHAC participants, NACI Secretariat, NACI HCID WG, NACI Voting Members. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting.

Agenda Item #2- Pfizer's Presentation

Presentation: COVID-19 Vaccine BNT162b2 Pediatric Information Update (uploaded to CNPHI)
Presented by: [redacted]

Pfizer presented their data and analysis on the COVID-19 Vaccine BNT162b2 focussing on safety, immunogenicity and efficacy in subjects 12-15 years old.

DISCUSSION/COMMENTS – Q & A with Pfizer

1. Can you clarify on the strategies at baseline that were used to determine whether or not individuals had exposure to COVID?

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Answer: At baseline, prior to vaccination, individuals were swabbed for PCR to see if they had active infection to COVID-19. In addition, serum was taken to look for antibodies to the N-antigen of SARS-Cov-2. If you were negative at baseline that meant that you had no history of symptomatic COVID-19, you were negative for N-binding and also negative for PCR at that visit.

2. Have you hypothesized for the reasoning between GMR (1.76) difference in ages 12-15 and 16-25 yrs of age? What would the GMR calculation be between these age groups and adults?

Answer: We have not calculated a GMR between this age group and adults because the assays were on a different time point. Whenever we compare two different groups, our policy is to run the samples that are part of the analysis at the same time, so that there is no variability into the agents of the assay. The reason it may be higher in the 12-15 year olds is that the younger you are; the higher the immune response seems to be.

3. Was it explicitly stated that no patients had a clinical syndrome that could be compatible with MIS-C. What about allergic events and anaphylaxis? The children recruited for the trial, were they attending school or were schools closed? Why was it only the N-antigen that you tested for at baseline?

Answer: In terms of MIS-C, participants were not allowed to have symptomatic disease, as part of the inclusion/exclusion criteria.

In terms of allergic reactions, there was an anaphalactoid reaction in a placebo subject: [redacted] Urticaria: 6 events total; 4 in placebo and 2 in vaccine group; placebo group participants had hives on days 1,2,3 & 10 for the vaccine group they occurred on days 3 and 5. Conclusion is that there is no obvious issue in this age group.

Data was collected from September to January. We did not collect information regarding schooling (stay-at-home, closed schools, etc.)

4. What variants of concern were circulating at the time of the data collection?

Answer: Variants from California, New York, UK, some cases of the South African variant, but majority was the Wuhan variant.

5. In the school group that you vaccinated, are you monitoring the social interactions in these age groups? Are you monitoring if they can transmit the infection?

Answer: Every two weeks they self-swab (nasal). We will have information from about 2300 children. Depending on the data, we may or may not be able to determine asymptomatic transmission.

6. Did the lymphadenopathy occur after a particular dose?

Answer: It can be seen after both the 1st and 2nd dose at all age groups. It wasn't so clear in the 12-15 year olds; but in adults it tended to happen after the 2nd dose..

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7. Any thrombocytopenia?

Answer: No adverse events for thrombocytopenia in both the 12-15 and 16-25 age groups. In the overall adult trial, I have to double check but I think there were 2 cases in the vaccine group and 3 cases in the placebo group.

8. Can you comment on the interval between the 1st and 2nd dose? What was the longest interval? Can you comment on the FDA timeline for approval?

Answer: Standardly its 21 days, but in adults we have data from our efficacy analysis of 41 days therefore the longest interval is 41 days. Pfizer is expected to receive feedback from FDA next week (week of May 10) and ACIP has called for a meeting on May 12. One of the main reason for the FDA delay, is that the safety signal from Johnston & Johnston occurred, and they had to prioritize that investigation.

9. Did you have an interval of longer than 28 days for the adolescents?

Answer: An answer could not be provided.

10. Are there any plans for a single dose trial?

Answer: No.

11. Did you collect data on more minor chronic medical conditions?

Answer: It was a wide variety of medical history in both adolescents and adults studies. What we were trying to do is allow general people into the trial to extrapolate from the trial to the general population. A medical history table is available in our submission.

12. Can you speak to the adverse event described of neuralgia abdominal pain and constipation; what was the severity and were interventions required?

Answer: [redacted]

13. Are you intending to study a 3rd dose in the adolescent and pediatric population? Would we be expecting to see safety and reactogenecity data on any more than 2 doses in this population?

Answer: This analysis is performed in the 16 years and more (i.e. those eligible in the adults study). At this time, there is no plan to extend the 3rd dose trial onto those populations, but that doesn't mean that we won't do it in the future. No 3rd dose data to be expected for now.

14. Were there any reports of pregnancy? Do you have any updates on safety in pregnancy?

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Answer: There were no pregnancy reports in the 15 year olds, and 1 in the 16-25 years. They are still pregnant, so we don't have the outcome yet. We are doing studies in other countries in pregnant woman; the vaccine is recommended on a risk-benefit analysis for that particular individual. ACIP has reported thousands of pregnant women receiving either Pfizer or Moderna vaccines. The safety profile is very similar to what we see in non-pregnant individuals. In addition, we are doing a study in pregnant women vaccinated at the gestational age of 24-33 weeks to observe the safety and immune response in pregnant women, as well as the transplacental transfer from the pregnant person to the neonate. We will be following the baby for many months to see their immune response.

15. When would you get results from the pregnancy outcomes?

Answer: This will depend on how enrollment goes. We currently have studies in US, UK, Brazil, South Africa, Mozambique and Spain. Some of the countries out of the US have not initiated yet (they might come on board in May). It may take sometime to get the information.

16. Some jurisdictions were providing a discretionary recommendation for the use of the vaccine in 12-15 years before the approval. Do you have real-life data or safety signals to share?

Answer: Vaccine for 12-15 years has been approved in Algeria and in Canada. We don't believe that there is any real-world data yet in this age group.

17. Can you provide more specifics on the grade 4 fever found in the 1 participant? Can you comment on analgesics; have you look at that or will you be looking at it?

Answer:

[redacted]

Analgesics were not used in a prophylactic way but used to treat fever. In the adult study about 30-40% tended to use analgesics more after the second dose than the 1st (See Questions 20 for further data).

18. Is there a plan to look at the effect of paracetamol prophylaxis especially with young children?

Answer:

In the pediatric study, this data will be collected in the e-diary, but there will not be a prospective study to access if the use of paracetamol before or at immunization decreases the vaccine response. We do not recommend prophylactic use of paracetamol.

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19. Can you comment on the potential myocarditis signal?

Answer:

Myocarditis and pericarditis were looked at in February and is being looked into now with the Israeli data that has been shared with us. We have been in talks with the Ministry of Health since the time the vaccine was used. All of the cases have been recently re-evaluated and will be included in the monthly safety report that is sent out to all health authorities, including Health Canada. We are conscious about sharing data that has not been shared with Health Canada yet. We can tell you that this is not something that has signaled from our data in terms of disproportionality analysis or with the observed to expected signal detection, and epidemiology work that we have been doing but we have provided a re-evaluation that will be submitted next week to Health Canada.

Action: Matthew Tunis to request Pfizer monthly safety report from Health Canada.

20. Antipyretic use in 12-15 year olds (follow up information to Question 17)

Answer:
After 1st dose: 36% reported antipyretic use
After 2nd dose: 50.8 % reported antipyretic use

No further questions were asked. WG Chair thanked Pfizer for the presentation. Pfizer members left the meeting (2:30pm).

Agenda Item #3- Discussion & Closing Remarks

[redacted]

Adjournment

The WG Chair thanked the WG and participants for their time and contribution.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

April 9, 2021 | 11:00am-1:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Bailey Beaudoin, Yung-En Chung, Leanne Coward, Pamela Doyon-Plourde, Kelly Farrah, Veronica Ferrante, Nicole Forbes, Anabel Gil, Shainoor Ismail, Christina Jensen, Ramya Krishnan, Christine Mauviel, Nima Mohamed, Austin Nam, Stephie Pierre, Kaeli Ramotar, Caroline Rodriguez-Charette, Natalie St. Pierre, Angela Sinilaite, Rob Stirling, Chantale Tremblay, Matthew Tunis, Man Wah Yeung, Eva Wong, Raphael Ximenes, Kelsey Young, Joseline Zafack (28)
	PHAC & HC Participants	Natalia Abraham, Helen Anyoti, Deborah Danoff, Kimberley Hutchings, April Killikelly, Celia Lourenco (HC), Angela Noble, Kelly Robinson (HC), Amanda Shaw, Bryna Warshawsky (10)
	NACI Members	[redacted]
	HCID Working Group Members	[redacted]
	AstraZeneca Participants	[redacted]
Total in Attendance	66	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests & Presentation

WG Chair welcomed working group members, PHAC participants, NACI Secretariat, NACI HCID WG, NACI Voting Members. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting. Presentation by NACI Secretariat followed.

Presentation: AstraZeneca COVID-19 vaccine Safety Signal: Risk of Thrombosis and Thrombocytopenia

[redacted]

The presentation provided the WG with updated data from countries and regulatory agencies on the AstraZeneca vaccine safety signal (VIPIT/VITT), including the new Canadian case. Discussion followed after the presentation from AstraZeneca.

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Action items: None

Agenda Item #2- AstraZeneca Presentation

AstraZeneca members joined the meeting (11:30am). WG Chair welcomed AstraZeneca before proceeding with the presentation.

Presentation: COVID-19 Vaccine AstraZeneca Update
Note: This presentation was also presented by AstraZeneca to PRAC/PRAC expert group
Presented by: [redacted]

AstraZeneca presented their updated data and analysis on the ChAdOx1 nCoV-19 (ASD1222) vaccine focussing on the following topics: Summary of cases of Thrombosis and thrombocytopenia, Thrombosis with thrombocytopenia, Potential mechanisms under consideration for Thromboembolic events with thrombocytopenia, Key data gaps and consideration on future research, Considerations for medical management on these rare events, and Next Steps.

DISCUSSION/COMMENTS – Q & A with AstraZeneca

1. How do you evaluate the risk-benefit without knowing and taking into consideration the epidemiology of where a person located? Can you comment on the following: If the treatment is IVIG, which has been in global shortage, there will be issues in low to middle income countries and remote areas.

   Answer: It's one of the limitations of the calculations of our observed to expected when you look at the incidence. The background events rate approach, is based on the descriptive cohort study that was done looking at particularly the US health insurance claim database. Looking at the data before the pandemic (01-Jan-2019 to 31-Dec-2019) on case definitions of thromboembolism plus thrombocytopenia, CVSTs, and CVSTs plus thrombocytopenia and then applying the different ICD codes for each case (ex. pulmonary embolism, portal vein thrombosis, etc.). This has its limitations being mainly based on the US population, and of course there are differences in healthcare systems, and genetic backgrounds. This is one of the areas that needs to be strengthen and gain more evidence. Collecting additional incidence rates and working with different collaborative research panels to generate additional proof.

   The second point around IVIG, it is important that IVIG is started as soon as possible once diagnosed, and therefore that's one of the areas that needs to be taken into consideration, as well as vaccination monitoring post the AstraZeneca vaccine.

2. Are the observed thrombocytopenia and thrombosis together? Are your 184 cases both thrombocytopenia and thrombosis (together)? If so, why did the EMA data show 180 cases and yours 184 cases?
   Answer: The 184 cases are the association of both thromboembolic with thrombocytopenia. The calculations are based on having thromboembolism with thrombocytopenia. EMA's calculation was thrombocytopenia with thromboembolic events, so there is intersection. Additionally, EMA may have calculated the cases mainly from Europe, whereas AstraZeneca calculated the cases from both Europe and the UK. There is a significant number in the AstraZeneca descriptions coming from the UK, and EMA only includes European cases in

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their analysis. For the observed to expected, it is for the association of the two of them, and that is one of the challenges that is faced. When looking at the data or the reference along the incidence of thromboembolism or thrombocytopenia isolated, there is quite significant amounts, but the association of both of them, makes it difficult to find the multitude of literature, so there are limitations in this calculation.

3. In terms of the comparative analysis, in Canada we are using predominantly mRNA vaccines, in the UK and in Europe there hasn't been association with the mRNA vaccine; when considering your mechanism of action did you take that into account (particularly with the spike protein analysis)?

   Answer: It's one of the question marks, whether this is something specific to AZ, adenoviral vaccines or all vaccines. Based on the cases described to date, it seems the rates are higher with the AstraZeneca vaccine than with the other mRNA vaccines. There are some anecdotal cases with the other vaccines but fewer. From the latest data, there were 15 cases of thromboembolism with thrombocytopenia with the mRNA Pfizer vaccine, but predominantly what is seen when talking about thromboembolism or thrombocytopenia being described as adverse events for the mRNA vaccines, they tend to be isolated and more with the peripheral members [limbs] like typical deep vein thrombosis. Initially it was thought there could be more of a selection bias. Most of the NITAGs in Europe recommended AstraZeneca vaccine to be predominately used in the younger age groups and the mRNA vaccines to be use predominantly in the older age groups. Because of the peak of the incidences of these conditions tends to happen around the 40s (47s), it was thought that because the AstraZeneca vaccine are mainly being used at this point in time then it does make sense that it might be related to this. The UK data showed that the AstraZeneca vaccine as well as the Pfizer vaccine was used predominately in the elderly population (quite even), so when looking at this distribution there isn't a trend towards similar distribution of cases between the AstraZeneca and the Pfizer vaccine. At this time it tends to be more frequent with AstraZeneca, but better understanding is still needed. When looking at other adenoviral vaccine that are currently available there's also some cases being reported, such as the 5 cases of J&J in Europe, but has significantly less number of exposure because the vaccine is almost not being distributed at all. It's too early to tell, but all hypothesis are being considered.

WG Chair thanked AstraZeneca for the presentation. AstraZeneca members left the meeting (12:15pm).

Agenda Item #3- Discussion & Closing Remarks

Discussion

Discussion was held highlighting the scarcity of evidence with no recommendations or conclusions made by the VSWG.

Adjournment

The WG Chair thanked the WG and participants for their time and contribution.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

January 13, 2021 | 1:00pm-3:00pm

Participants	**Working Group Chair:**	[redacted]
	Working Group Members:	[redacted]
	NACI Secretariat	Oliver Baclic, Christina Jensen, Ramya Krishnan, Kaeli Ramotar, Joseline Zafack (5)
	PHAC Participants	Helen Anyoti, Bryna Warshawsky (2)
Regrets:	[redacted]	
Total in Attendance	17	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests

WG Chair welcomed working group members, PHAC participants, and NACI Secretariat. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting.

Action items: None

Agenda Item #2- Presentation of Allergic Events following COVID-19 Vaccines

Presented by: Joseline Zafack

NACI Secretariat presented a brief overview of the current data on allergic reactions to polysorbates and tromethamine, and discussion regarding proposed updates to the NACI recommendations was held.

No material was distributed to members for this presentation.

DISCUSSION/COMMENTS

1. Discussion around not referring to/listing polysorbates as a vaccine allergen in the NACI recommendations. Members agreed that at this stage, because polysorbates are not an ingredient in the current approved vaccines they should not be listed as a potential vaccine component allergen in the NACI recommendations. The question might be reassessed if other vaccines are authorized where polysorbates are an ingredient. Members raised points regarding:
    a. polysorbates being listed as a non-allergen in CIG in vaccines for which polysorbates are an ingredient: a participant said there is a footnote under the table in CIG specifying

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that *«Any component in a vaccine may be a potential allergen. This table identifies most common allergens; adjuvants and preservatives may be potential allergens, but this is extremely rare»* so the group agreed at this time no changes were required to CIG.

b. The fact that some Canadian jurisdictions have released information referring to polysorbates as a potential allergen. There might be a need to communicate with P/Ts to make sure the information is consistent. The issue of inconsistent guidance had the potential to cause vaccine hesitancy.
c. CDC guidance documents referring to polysorbates and the difference in US/Canada guidance and differences in US/Canada medical system.

2. Discussion around referring or not referring to tromethamine anywhere in the NACI recommendation based on the 1 reported anaphylaxis reaction. Members raised points regarding:
    a. Acknowledging it since there was 1 case reported. It was noted than even though there was only one case report identified, the condition might be underestimated as people were not aware and did not look for it.
    b. Do not lump it with PEG, as there is an option to choose the vaccine brand which does not contain tromethamine.
3. NACI recommendations (contraindications): Change the wording of «vial» to «container»:
    a. Pharmacy wording uses container (Packaging refers to the box)
    b. Some vaccines may come in pre-loaded syringe; best to use container to cover future vaccine forms
4. NACI recommendations (precautions in individuals with mild to moderate immediate allergic reactions): the wording will be revised *from «Assessment by an **allergist may be** warranted prior to re-immunization»* to *« Assessment by a **physician or nurse practitioner is** warranted prior to re-immunization»*. Allergists are still included in physicians; the new wording gives more flexibility about who should assess the patient (e.g. depending on the severity of the previous allergic reaction and availability of specialists in different jurisdictions).

Action items: NACI Secretariat will redraft recommendation based on members' feedback and will circulate to NACI members for comments.

Agenda Item #3- Upcoming NACI-VSWG Activities

NACI Secretariat explained that the VSWG will be hosting AstraZeneca at the next meeting on Monday January 18th, 2021 (11am-1pm EST), as AstraZeneca will present their vaccine safety data/analysis. The meeting has been opened to NACI Voting Members and the NACI-HCID WG.

NACI Secretariat mentioned they have been reviewing the CIG Chapter on contraindications and precautions, and will share the document to the WG for review and comments.

There was no presentation for this discussion.

DISCUSSION/COMMENTS

Action items: NACI Secretariat to share CIG Chapter review to WG.

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Adjournment

The WG Chair thanked the WG and participants for their time and contributions.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

January 18, 2021 | 11:00am-1:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Veronica Ferrante, Shainoor Ismail, Christina Jensen, Ramya Krishnan, Kaeli Ramotar, Matthew Tunis, Kelsey Young, Joseline Zafack (9)
	PHAC Participants	Helen Anyoti, Amanda Shaw, Bryna Warshawsky (3)
Additional Participants	**NACI Members**	[redacted]
	HCID Working Group Member	[redacted]
	AstraZeneca Members	[redacted]
Regrets:	None	
Total in Attendance	45	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests

WG Chair welcomed working group members, PHAC participants, NACI Secretariat, NACI HCID WG, NACI Voting Members, and AstraZeneca members. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting.

Action items: None

Agenda Item #2- AstraZeneca Presentation

Presented by: [redacted] AstraZeneca Medical Advisor, Respiratory and Immunology

AstraZeneca presented their data and analysis on the ChAdOx1 nCoV-19 (ASD1222) vaccine focussing on the following topics: Exclusion criteria of trials, assessment and impact of pre-existing immunity to the adenovirus vector, data for the observed occurrences of transverse myelitis, Bell's palsies and other

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adverse outcomes, neuroinflammatory disorders and SAE that were reported, assessment or probability of the potential for adenovirus disease (i.e. Reversion to wild type and/or recombination with endemic adenoviruses), assessment or probability of oncogenesis, anaphylaxis and allergic events which occurred following immunization, safety profiles by age groups and sex, and safety in pregnant women and special populations.

DISCUSSION/COMMENTS – Q & A with AstraZeneca

1. *Does the anaphylaxis exclusion include anaphylaxis to anything in the past or is there a specific allergen?*
   Answer: It includes anaphylaxis to any of the specific ingredients of the vaccine.

2. *Why do patients with HIV not fall into the immunosuppressant exclusion category?*
   Answer: Patients had to be on therapy for at least 6 months, so they had to have a suppressed viral load and there was a cd4 criteria of over 350 for them to be enrolled in the trial; uncontrolled HIV were not included.

3. *Why was there less reactogenicity with the second dose, when generally there is more?*
   Answer: Can't reply definitively. It's a feature of the vaccine and what has been observed. There are many theories as to why this happens, but it has been seen in other adenovirus vaccine platforms as well.

4. *Did you see a reduced reactogenicity after the second dose after all age groups?*
   Answer: It was seen across both younger and older age groups.
   Action: AstraZeneca to send VSWG published data for those responses.

5. *As per the case of transverse myelitis, should previous GBS be a CI or precaution to the vaccine?*
   Answer: [could not answer]
   Action: AstraZeneca to discuss with global colleagues and will provide the VSWG with a response.

6. *Are DART (developmental and reproductive toxicology) data available?*
   Answer: This information is available in the HC submission package

7. *(See #5 Repeat) As per the case of transverse myelitis, should previous GBS be a CI or precaution to the vaccine?*
   Answer: We have submitted our proposed product monograph to HC and it's currently under review. In terms of contraindication, the only contraindication that we have submitted is in regards to any hypersensitivity to any of the medicinal ingredients in the formulation. Beyond that, AstraZeneca has not proposed any other contraindications as part of the label.

8. *Is it documented that there is no shedding of the virus?*
9. **Answer**: That has not been looked at. There will be swabs taken in the COV005 trial, but in terms of active surveillance of shedding that is not something that has been reported yet. There is a paper in a pre-print server showing reduced nasal shedding against the d614g variant in not human primates and rodent models. That is something that has been pre-published and we will be looking at that more closely.
   Action: AstraZeneca to share the data with the VSWG

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10. *For patients with the transverse myelitis, is there documentation of intrathecal viral vector antibodies production within the CSF?*
    Answer: No those samples have not been looked at.

11. *Have there been any data/experiences from the UK shared with AZ, in regards to post-implementation safety profile to date (especially anaphylaxis and neuroinflammatory events)?*
    Answer: So far we have not received reports like that yet.
    Action: AstraZeneca to provide the VSWG with information as it comes up

12. *Do you know what the upper age was for individuals over 70 years of age? What age limit (if any) are you seeking for the approval?*
    Answer: There wasn't an upper limit set on age. All we have data cut for is over 65 and over 70. In terms of our proposed label, we are requesting an indication for patient population over 18 years and that is the indication that is currently under review with HC.

13. *Can you give more background on your upcoming trials with children?*
    Answer: There is a cohort that will enroll children aged 5-12 years that will be part of the COV002 study in the UK. Enrollment will not start until the summer. We have a paediatric investigation plan that has been agreed upon with the EMA that is currently posted on their website.
    Action: AstraZeneca to provide VSWG with a link to that website.

14. *Is there data for ages 12-17 years?*
    Answer: That is not part of the clinical trial plan, but we will have to look at the EMA plan to see if they are included there. As part of the phase 3 clinical trial, 12-17 is not included there.

15. *(Follow-up to above) Odd, no?*
    Answer: The immune responses for adolescents are different than adults, and therefore more study has to be done in adults aged 18+ before any dose recommendations can be made for 12-17. We are looking at that in the future, but as of right now it's the differences in the developing immune systems of adolescents that is delaying analysis.
    Action: AstraZeneca to let the VSWG if any future trials for the 12-17 age group are set.

16. *The one case of transverse myelitis, was there a fall involved with that?*
    Answer: Essentially it was a case of a fall and sequelae related to the fall. In some of the literature it is considered a case of myelitis instead of transverse myelitis because it is short segmented. It is up to different neurologist interpretations, so there is a potentially alternative cause for the case.

17. Are there any trials planned for pregnant women?
    Answer: There is no active trial for pregnant women, but in cases like this pregnant woman will be part of surveillance studies and pregnancy registries. That is being discussed in the UK and US.

18. *In the UK, are you currently tracking pregnant women opting for vaccination or is it still being set up?*
    Answer: It is still being setup.

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19. *Any trials planned for immunocompromised individuals?*
    Answer: So far we have not seen specific trials for these individuals.
    Action: AstraZeneca to inform the VSWG if these trials begin.

20. *Will there be a pregnancy registry set up in Canada as well?*
    Answer: If the vaccine is approved, yes. It is under consideration for Canada.

21. *In the product contents, any precautions for the polysorbate 80?*
    Answer: There is no specific importance given to polysorbate 80; it's another of the ingredients. There is no cross-reactivity noted with polyethylene glycol either.

22. *What is the purpose of the L-histidine?*
    Answer: It is a PH stabilizer.

WG Chair thanked AstraZeneca for the presentation. AstraZeneca members left the meeting.

Action: Secretariat to upload AstraZeneca presentation and HC submission package to HCID and VSWG folders on CNPHI

Agenda Item #3- Closing Remarks

WG Chair asked if there were any additional questions. NACI Voting member asked if the potential cross-reactivity between PEG and polysorbates has been discussed in the VSWG in terms of the risk for allergy and anaphylaxis. This topic has been discussed at previous WG meetings and if the AstraZeneca vaccine is approved, members will revisit the topic.

Adjournment

The WG Chair thanked the WG and participants for their time and contributions.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

May 19, 2021 | 1:30pm-3:30pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Kelly Farrah, Nicole Forbes, Christina Jensen, Ramya Krishnan, Kaeli Ramotar, Matthew Tunis, Kelsey Young, Joseline Zafack (9)
	PHAC & HC Participants	Natalia Abraham, Kimberley Hutchings, Su Hyun Lim, Amanda Shaw, Tonja Stothart (HC), Bryna Warshawsky (6)
Total in Attendance	24	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests

WG Chair welcomed working group members, PHAC participants, and NACI Secretariat. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting.

Agenda Item #2- Overview of the Evidence (presentation)

Presentation: Update on vaccine safety activities (uploaded to CNPHI)
Presented by: NACI Secretariat, Joseline Zafack

NACI Secretariat presented the updated data on VITT, an overview of AEFIs being monitored, and outlined upcoming topics of discussion.

Q&A:

1. Do we know of any other countries using second doses of AstraZeneca?
   Answer: (Additional Slide presented); yes, as of April 23, 2021, UK, Australia, Bulgaria, Ireland, Italy, Netherlands, EMA, Austria, Cyprus, Latvia, and Lithuania have been recommending 2 doses of AstraZeneca. More recent information on countries' recommendations can be found in the ECDC technical report «Overview of EU/EEA country recommendations on COVID-19 vaccination with Vaxzevria, and a scoping review of evidence to guide decision-making, 18 May 2021 (see Table 1).

2. On the topic of menstrual irregularities, is there any mention of the possibility of these woman being early pregnant?
   Answer: No, this hypothesis was not mentioned.

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Agenda Item #3- CAEFISS data (presentation)

Presentation: Update on vaccine surveillance activities
Presented by: PHAC Vaccine COVID-19 Surveillance Division, Natalia Abraham

Verbal update on PHAC safety surveillance data (CAEFISS and CVD):

VITT

- As of May 12, 28 cases of thrombosis with thrombocytopenia in Canada
  - 18 confirmed to be positive with anti PF4 antibodies (considered to be VITT)
  - The remaining have results that are pending or it is unknown if a laboratory test was ordered
- From a surveillance perspective, reviews of these cases/entities are being done to identify consistency with a causal association using WHO guidelines for causality and AEFIs
- Time to onset ranged from 6-24 days after vaccination
  - This will expand from cases not technically in the system (jurisdictions have been giving PHAC early notification by email)
- All cases are after dose 1
- Majority of cases following AstraZeneca were female
- Majority of cases following COVISHIELD were male
- Based on evidence to date, Canadian VITT rate is 1 in 83,000; but if pending cases turn out to be positive the rate could be as high as 1 in 55,000
- There are very few doses of COVISHIELD left in Canada, so any cases that occur in the coming weeks, will make the COVIDSHIELD rate higher
- In the news, there have been 15 cases reported on, of which 3 were deaths: Alberta, New Brunswick and Quebec

Myocarditis

- 17 cases
  - 3 cases not with Pfizer vaccine
- Comparative analysis shows more cases with Pfizer vaccine
- Unlike the cases in Israel, most of the cases in Canada are in females and not clustering in the younger age groups; cases occurred mostly after dose 1 (this doesn't mean much as most people have not received their 2nd dose)

Q&A: No questions asked.

Agenda Item #4- CANVAS data (presentation)

Presentation: Canadian National Vaccine Safety (CANVAS) Network: Active Safety Surveillance for COVID-19 Vaccines: Bell's Palsy (uploaded to CNPHI)
Presented by: VSWG Chair, [redacted]

VSWG Chair presented preliminary data on Bell's Palsy surveillance in CANVAS.

Q&A:

1. [redacted] transient facial weakness/numbness, have you been noticing similar trends?
   Answer: This may be captured in paresthesia, which is a separate symptom in the survey. When we do this for influenza (H1N1, seasonal) we do see it emerge. We can take a closer look at it and see what the rates are looking like in the COVID-19 vaccines in CANVAS.

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Agenda Item #5- Discussion

VSWG members would like to see more information around safety signals in children, specifically MIS-C; as well as around menstrual irregularities.

Action Items: VVWG to provide VSWG with VITT definition (**actioned**; uploaded on CNPHI)

Adjournment

The WG Chair thanked the WG and participants for their time and contribution.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

February 16, 2021 | 1:00pm-3:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Christina Jensen, Ramya Krishnan, Kaeli Ramotar, Joseline Zafack (5)
	PHAC Participants	Helen Anyoti, Kimberley Hutchings (2)
Regrets:	[redacted]	
Total in Attendance	14	

Agenda Item #1- Welcome and Introduction- Agenda, Declaration of Interests, New VSWG Member

WG Chair welcomed working group members, PHAC participants and NACI Secretariat. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting. The new VSWG member [redacted] will be introduced at the next meeting.

Action items: None

Agenda Item #2- Sharing Documents within VSWG

NACI Secretariat outlined the following document sharing procedures with the VSWG:

- Meeting materials and confidential information will be uploaded to CNPHI in the meeting folders. This information should not be shared further.
- Links that are opened to the public will be shared via email and can be shared with others
- A new folder entitled "Additional Information" will be added to CNPHI and will contain extra material (news reports, study results, etc.) relating to vaccine safety. These documents will not necessarily be discussed with the WG, but serve as supplementary knowledge for WG members

Action items: NACI Secretariat to create "Additional Information" folder on CNPHI and distribute the CNPHI link to WG Members.

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Agenda Item #3- Swelling (related to dermal fillers) following COVID-19 Vaccines

Presenter: Joseline Zafack

NACI Secretariat presented a brief overview of the current data on delayed inflammatory reactions (DIR) to hyaluronic acid (HA) dermal fillers following COVID-19 vaccines.

Discussion Questions:

1. Is this a temporal association rather than an actual vaccine adverse event?
2. Do we want to change any of the language in the current statement around this?
3. How much of this is a reaction related to the actual dermal filler injection vs a reaction to the vaccine?

Discussion:

- Members brought up the use of hyaluronidase under other circumstances (ex. Injection of hyaluronidase into knee for osteoarthritis).
- Questions for Allergist: Do we know among people who get cosmetic fillers, what portion get reactions when they get re-exposed to hyaluronic acid? Could sensitization be the mechanism?
- Hyaluronic acid is used in a number of procedures and added ingredients. To date, there is not enough information to make a decision to the above discussion questions.

Action Items: WG Member, Deborah Danoff, to share information from HC relating to swelling and dermal fillers. NACI Secretariat to relay discussion/questions to WG Allergists (unable to attend meeting) via email for their input and expertise. NACI Secretariat to upload presentation to CNPHI. The WG will keep on monitoring and collect more information.

Agenda Item #4- Immune thrombocytopenia following COVID-19 Vaccines

Presenter: Joseline Zafack

NACI Secretariat presented a brief overview of the current data on immune thrombocytopenia following COVID-19 vaccines.

Discussion Questions:

1. How likely do we think this could be linked to the vaccine versus the myriad of other factors that cause this?
2. Potential Research Questions: How likely would it be after this type of vaccine and what would the mechanism be behind it?

Discussion:

- Members brought up that there could be a biological plausibility. ITP can occur with other infections and other vaccines.
- There is not enough information to consider that ITP is causally related to the COVID-19 vaccines. There are many other etiologies and incidence of ITP among COVID-19 vaccinees is within the expected background rate.

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Action Items: NACI Secretariat to follow up with vaccine safety section regarding background rates and experience with other vaccines. NACI Secretariat to upload presentation to CNPHI.

Agenda Item #5/6- Upcoming NACI-VSWG Activities & Closing Remarks

NACI Secretariat reminded WG to review and comment on the CIG chapter that was sent to them the week prior, provided the WG with an update on the Janssen and Novavax vaccines timelines, and shared potential future meeting topics: Janssen and Novavax safety data, safety of mixed-matched vaccine schedules (use of more than 1 COVID-19 vaccine), reactogenicity in patients with previous SARS-CoV-2 infection, AEFI: delayed local reactions («COVID Arm») following COVID-19 vaccination.

Potential Date for Janssen vaccine safety presentation: March 1, 2021 (Has not been confirmed).

Action Items: NACI Secretariat to provide WG members with the safety data for Janssen and Novavax as it comes in and preferably before presentations. NACI Secretariat to send out a summary of the article from France, and upload the actual article to CNPHI

Adjournment

The WG Chair thanked the WG and participants for their time and contributions.

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National Advisory Committee on Immunization

Record of Decisions

Thursday, April 15, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
April 15, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics, no conflicts of interest were declared.	• Agenda for April 15, 2021 was reviewed and approved.
2.	**Presentation: Vaccine Supply Update, Risk Benefit Analysis, Epidemiological Update** *For Information* (Presenters: Bryna Warshawsky, Eva Wong, Joseline Zafack, Shainoor Ismail)	The presenters from the NACI Secretariat provided an update on Canada's vaccine supply, an overview of the benefit-risk assessment and proposed recommendations on the use of COVID-19 vaccines. Items covered by this presentation included: • Vaccine update supply: A large supply of mRNA vaccine will be arriving over the next few weeks. Although there is a delay in the shipment of the Moderna vaccine [redacted] the supply of both Pfizer and Moderna vaccine remain secure and is expected to further increase in the coming weeks. The presenter noted that efforts are being made to supply the vaccine earlier. • Benefit-risk assessment of VITT for AstraZeneca (AZ) vaccine using a similar approach to the UK analysis with Canadian data. The scenarios used in the age-based analysis include 'low event' (public health measures implemented) and 'high event' (public health measures not implemented). The presenter shared graphs for the analysis of the low/high events scenarios that could have been prevented by the use of AZ vaccine, using fixed and age-based rates juxtaposed to risk of VITT. • An overview of the proposed NACI recommendations on the use of COVID-19 vaccines (mRNA, viral vector) with a special focus on recommendations for the second dose and the age restriction. • Results from a public a survey which demonstrated a reduction in the proportion of individuals who wanted to receive a vaccine as soon as possible from 61% in January to 48% in April; however, the proportion of individuals who did not want to receive any vaccine has remained stable. The presenter also provided a summary of the factors to consider in the risk-benefit	N/A

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		analysis for who to offer the AZ/Janssen vaccine in the context of limited mRNA vaccine supply. Following the risk benefit analysis, the following was presented: 1. Proposed recommendations on Janssen (aligned with AZ) and the risk assessment framework. 2. Proposed recommendations on the second dose of COVID-19 vaccine to be offered to individuals under 55 years of age who have been vaccinated with AZ. 3. Proposed recommendations on contraindications to COVID-19 vaccination for individuals with a history of VITT	
3.	**Update from CDC on ACIP and regulatory process** *For Information* *(Presenter:* [redacted]	The presenter from the CDC provided an update on the discussions held at the April 14, 2021 CDC-ACIP meeting. • ACIP reviewed Janssen's safety data from their clinical trials. • The CDC and FDA recommended a pause on the use of the Janssen COVID-19 vaccine following reports of 6 cases of CVST with thrombocytopenia and provided a brief summary of a few cases. • The ACIP decided on delaying making recommendations and will be reconvening at a later date once more data is available, including a risk-benefit analysis and further details on the cases.	
4.	**Discussion on AZ and Janssen Recommendations** *For Discussion/Decision* All	There was discussion with NACI members on: What age restrictions (if at all) does NACI now want to set for the use of AstraZeneca (AZ) vaccine (currently recommended in people 55 years or older only)? Ideas that members proposed include the following: • NACI should not set an age limit given Canada's current large supply of mRNA vaccines and ability to deliver those vaccines to older people; instead, NACI could create a permissive statement to allow each province/territory (P/T) to set their own age limit. However, there might be challenges in balancing individual autonomy vs. P/T rollout/implementation. • Others countered that it would be important for Canada to have a unified age limit across the country, while still allowing individuals to choose to receive the AZ vaccine after risk-benefit assessments and informed discussions have taken place. • The recommendation should be focused on burden of disease (i.e. incidence of COVID) instead of age (which is itself integrated within the epidemiology); NACI could consider	• **Consensus:** 11/13 voting members agree to develop an age limit for regions where there is a high enough incidence of COVID-19 to be able to use the AZ vaccine (e.g. if incidence rate is lower than X, then the jurisdiction may not need to use this vaccine at all; and if the incidence rate is higher than Y, then

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having different recommendations for jurisdictions with different burden of disease (e.g. recommend that AZ vaccine not be used in a jurisdiction with a very low incidence of COVID-19).

- Having also reviewed the graphs for the hospitalization and death outcomes, some suggested using the Management Options table to provide separate options for areas with high vs. low incidence of various outcomes.
- It would be important for NACI to clearly communicate that any age limits in NACI's recommendations on AZ vaccine is based on the risk of COVID-19 and not on the risk of VITT, given that it would be incorrect to interpret that there is no risk of VITT in individuals 55 years and older. NACI should recommend either a very low age limit (e.g. 30) or no age limit at all.

the jurisdiction may consider use of the vaccine within a certain age limit). The age limit will be decided after NACI reviews the updated modelling analysis.

The committee debated on this recommendation option: Remove the age limit in the recommendation but refer readers to the Management Option table, where "high risk" jurisdictions would be able to use the AZ vaccine if necessary (Co-Chairs will work with the NACI Secretariat to determine the level of disease burden that would clearly define "high risk/high incidence areas").

[redacted]

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		[redacted]	
5.	**Next Steps** *For Information* (Presenter [redacted])	NACI Secretariat will conduct a new modelling analysis with a fixed rate of VITT and risk of COVID-19 daily incidence rate of 3 and 6 per 10,000 to simulate varying low incidence rates across Canada.	• The updated analysis and recommendations will be circulated to NACI members by email.

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National Advisory Committee on Immunization

Record of Decisions

Thursday, April 20, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
April 20, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics, no conflicts of interest were declared. Additionally, the NACI chair: • Provided and update on AZ publishing timeline and inclusion of a sensitivity analysis surrounding ICU data.	• Agenda for April 20, 2021 was reviewed and approved.
2.	**2.0 Janssen Benefit-Risk Recommendations: Discussion and next steps** *For Discussion / Decision* *(Presenter:* Eva Wong, Shainoor Ismail*)*	The presenters from the NACI Secretariat presented a benefit-risk analysis by age group, proposed recommendations on the use of viral vector COVID-19 vaccines and EEFA considerations. Items covered by this presentation included: • Update on methodology for benefit risk analysis approach including considerations surrounding variables and data sources and assumptions and limitations. • Benefit / risk analysis of use / non-use of Janssen vaccine and impact ICU admissions and deaths due to VITT vs. due to COVID-19 infection. Impact of VOCs were also presented. • Evolution of NACI age based recommendations for AZ vaccines. • Proposed recommendations and ethical considerations related to the AZ safety signal. Following the presentation, clarification was provided on the following points: • Sensitivity analysis around VE, rate of VITT and ICU admissions. • Assumption that 100% of VITT cases become ICU admissions, and current accuracy. • Wait times have not been adjusted for the Janssen supply in Canada and adjustment will need to be incorporated.	• NACI secretariat will send the updated sensitivity analysis tables.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	2.1 Discussion on Janssen Recommendations *For Discussion / Decision* All	Following the presentation, there was a discussion regarding whether AstraZeneca and Janssen vaccines should be aligned in the NACI COVID-19 vaccine recommendations. • Members raised concerns about the prematurity of making a Janssen recommendation at this time. ACIP, FDA and EMA will publish their recommendations later this week and members were supportive of waiting for ACIP and FDA recommendations. No changes should be made to the current wording. • A member raised the importance of incorporating efficacy comparability by dose in the benefit-risk analysis. The current analysis is based on 1 dose only. NACI secretariat will propose an approach to incorporate this factor. • Context on the anticipated COVID-19 vaccine supply for each type of COVID-19 vaccine for each vaccine was provided. Members discussed the updated sensitivity analysis table for the AZ (base case, all strains, VOC only) with wait-time vaccine. • Clarification regarding the hospitalization outcome: the cases of VITT were underreported and the number may have been lower due to cases currently under investigated. • Overall, it appears that the benefit of AZ is greater than the risk of waiting for MNRA vaccine in all age groups, which is consistent with ON and UK data.	• The committee will continue their deliberations on Monday, April 26, 2021, from 1:00 PM – 3:00 PM EST (2 hours). • In response to a member query, NACI secretariat to ask PHAC Surveillance Branch how death data is ascertained.
3.	**Pregnancy Update** *For Information* (Presenter: Christina Jensen)	The presenter from the NACI Secretariat provided an update on COVID-19 vaccination during pregnancy and breastfeeding Items covered by this presentation included: • Brief summary of the recently published SOGC statement calling on Ontario and other provinces to prioritize COVID-19 vaccination in women more than 20 weeks pregnant • Overview of NACI's current COVID-19 recommendations and emerging safety/immunogenicity evidence for pregnant/breastfeeding persons. • Next steps for updating NACI recommendations for COVID-19 vaccination in pregnant/breastfeeding persons and items to cover at a forthcoming NACI meeting.	• Update evidence on safety and immunogenicity of COVID-19 vaccination in pregnant/breastfeeding women in the NACI recommendations from "absence of" to "limited" evidence. • Topics to be presented at a forthcoming NACI meeting: PHAC epidemiological data on COVID-19 among pregnant persons in Canada, scan of international recommendations in pregnancy and breastfeeding, re-visit NACI guidance on COVID-19

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		Following the presentation, members deliberated over the following: • Which type of vaccine should be recommended for the pregnant and breastfeeding population (e.g., only mRNA). This will be further discussed at a future NACI meeting. • Whether the increase in the number of confirmed cases and ICU admissions in pregnant persons in Ontario may be due to the increasing number of COVID-19 cases attributed to variants (B1.1.7 or P1) or the overall increase in COVID-19 incidence. ○ [redacted]	vaccination in pregnant/breastfeeding women and other special populations, and revisit interval from series completion to conception. • ARCHE review will be updated by end of June for all special populations.
4.	**4.0 Presentation: Recommendation for action when minimum interval between COVID-19 vaccines doses is not adhered to** *For Information* (Presenter: Christina Jensen)	The presenter from the NACI Secretariat presented an update on recommendations addressing actions when minimum intervals are not respected. Items covered by this presentation included: • Domestic and international recommendations on the minimum interval between COVID-19 vaccine doses • Points for consideration: the lack of safety data for the administration of more than 2 doses; product monographs do not address what to do if the minimum interval is not respected; concerns relating to adverse events and vaccine supply. • Proposed recommendation (included in Table 2) to advise against repeating a dose if given earlier than recommended.	
	4.1 Discussion *For Discussion / Decision* All	Following the presentation, clarification was provided on the following points: • ACIP's recommendation to not repeat the dose from December was issued in the context of limited vaccine supply and limited evidence evaluating potential adverse events of administering doses in close succession. ACIP will revisit this recommendation as evidence emerges on this issue. • There are various scenarios that should be considered when making a recommendations regarding deviations from the minimum interval(I.e. a day before the minimum vs. 24 hours after the first dose).	• The presenter from the NACI Secretariat will consult with immunologists from the group to address the issue of administering doses earlier than the recommended interval in a future NACI statement.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
5.	**5.0 Presentation: Revision of AstraZeneca Recommendations** *For Information* (Presenters: Austin Nam, Shainoor Ismail)	Individuals from the NACI Secretariat presented the following: • Updates to the AZ risk-benefit tables using a revised approach: previous base case risk analysis estimating the benefits of preventing COVID-19 related ICU admissions vs. the revised approach estimating the benefits of using AZ, considering five different COVID-19 activity scenarios. • Proposed NACI recommendation for the use of AZ vaccine in individuals 30 years and above, if there is no desire to wait for an mRNA vaccine and an overview of the risk assessment framework. Following the presentation, members deliberated on the following: • Whether the revised tables should represent the new base case and if there is a need for an intermediate scenario. It was noted that there is no need for the tables to become the new base case, as data from Ontario is still being extrapolated to the rest of Canada. It was also suggested to present both scenarios; however a member raised the concern that presenting more than one scenario could cause confusion. • Whether obtaining datasets from provinces/territories is warranted. A member suggested keeping the recommendation broad and using the lowest scenario and the highest scenario for the recommendation. If available, P/T data, will be sent to the secretariat to assess if the ICU admission rate in ON is significantly different.	
	5.1 Discussion *For Discussion / Decision* All	• There was discussion with NACI members on the proposed recommendation to offer the AZ to individuals 30 years and above without contraindications, who do not wish to wait for an mRNA vaccine. Nine out of twelve members voted in favor of maintaining the threshold of 30 years and above. • The recommendation for pregnancy has not yet been decided; however, an overall preferential recommendation for mRNA has been made.	• Replace "may" with "should" in the note following the recommendation directing provinces/territories to adapt the age limit based on their local epidemiology • Some members from the group will reconvene to further discuss ICU data.

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National Advisory Committee on Immunization
Record of Decisions
Thursday, April 20, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
6.	**Next Steps** *For Information* (Presenter: Matthew Tunis)	The next NACI Meeting is scheduled for Monday, April 26, 2021 at 13:00 – 15:00 EST.	

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National Advisory Committee on Immunization

Record of Decisions

Monday, April 26, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for April 26, 2021 was reviewed and approved.
2.	**2. Presentation: Janssen Benefit-risk and Recommendations** *For Information* (Presenters: Joseline Zafack, Kelsey Young, Shainoor Ismail)	The presenters from the NACI Secretariat provided an update on the current context for Janssen, an overview of the benefit-risk analysis, and the proposed NACI recommendations for the Janssen vaccine. Items covered by this presentation included: • Key updates on the Janssen vaccine and reported thrombosis with thrombocytopenia syndrome (TTS) cases discussed at the April 23, 2021 Emergency ACIP meeting. Fifteen cases of TTS have been confirmed, all occurring in women (13 cases <50 years old). Additional potential TTS cases are currently under investigation, which could potentially include male cases. • Domestic and international recommendations on age limits for the use of Janssen COVID-19 vaccine. • Benefit-risk analysis comparing the benefits of preventing COVID-19 related ICU admissions and deaths while waiting for an mRNA vaccine to the risk of VITT after administration of Janssen. The analysis used the same methods applied for the AZ benefit-risk assessment and will vary each week as the wait time for mRNA vaccines shortens. • Update on the confirmed VITT cases in Canada (as of April 22, 2021) o There are 5 confirmed cases of VITT reported in the following provinces: [redacted] Four suspect VITT cases are currently under review and will bring the total count to nine cases if they are confirmed.	

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National Advisory Committee on Immunization

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Monday, April 26, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Proposed recommendations for the use of Janssen vaccine with a brief summary of factors to consider in the risk assessment framework. • Summary of forthcoming updates to the NACI COVID-19 statement. NACI will review recent evidence on vaccine use in groups under-represented in clinical trials (immunosuppressed, pregnant/breastfeeding, autoimmune) and reassess recommendations if warranted.	
	2.1 Discussion and Approval: Janssen Recommendations *For Discussion / Decision* All	[redacted] Members discussed the preferential recommendation for mRNA vaccines in special populations (immunosuppressed, pregnant/breastfeeding, autoimmune) and whether it should be additionally highlighted for each group. Members agreed to maintain the current recommendations for the immunosuppressed and autoimmune population until the evidence is reviewed next week. In addition, 10 out of 10 members agreed to the following; emphasize the preferential mRNA vaccine recommendation for pregnant women, as they are now identified as a high risk group; change	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		the qualifying language in light of the growing evidence (i.e. registries); and use the 4 papers summarizing the evidence and why mRNA is recommended for this population over other vaccines. Liaison members noted that the management of VITT poses additional challenges in pregnancy and that permission for AZ should be maintained considering it could be beneficial in areas where there is a higher incidence and risk of COVID-19.	
3.	**3. Next steps and upcoming COVID-19 workplan items** *For Information* (Presenter: Matthew Tunis)	The next NACI meeting is on May 4, 2021 from 11:00-12:30 EST.	

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National Advisory Committee on Immunization

Record of Decisions

February 24 & 25, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
February 24, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* [redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for February 24 & 25, 2021 reviewed and approved.
2.	**2a. Public Health England (PHE) Vaccine Effectiveness Follow-up Data** *For Information* [redacted] PHE)	The presenter from Public Health England (PHE) provided an update on vaccine effectiveness and impact of the Pfizer and AstraZeneca COVID-19 vaccines in the targeted vaccinated groups. The presentation covered the following themes: [redacted]	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	2b. Institut national de santé publique du Québec (INSPQ) Vaccine Effectiveness Follow-up Data *For Information* [redacted] INSPQ)	Data from INSPQ was shared regarding the surveillance-based assessment on the effectiveness of a first dose of mRNA vaccine against COVID-19 in health care workers (HCWs) and long-term care facilities (LTCF) residents in Québec. [redacted] During the question period, the presenter provided clarifications on: • [redacted]	
	2b. BCCDC Vaccine Effectiveness Data *For Information* [redacted] BCCDC)	[redacted]	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted]	
3.	**Regulatory Update on AstraZeneca** *For Information* (Celia Lourenco, Health Canada)	The presenter provided an update on the regulatory review and anticipated authorization of the AstraZeneca COVID-19 vaccine. Additional information was provided regarding review process and anticipated authorization of Varity Pharmaceutical's Covishield vaccine. Covishield is manufactured under a licensing agreement with AstraZeneca by the Serum Institute of India (SII). Items covered by presentation included: • Outline of approval process, and anticipated indications for the AstraZenca COVID-19 vaccine, • Additional real-world evidence considered in the regulatory decisions for authorization of AstraZeneca COVID-19 vaccine (Scottish study), • Due to comparable vaccine quality, Covishield vaccine will be authorized using AstraZeneca clinical trial results. Discussion following the presentation covered topics such as: [redacted] • Rationale, evidence, and quality evaluation process for authorization of Covishield vaccine Members raised the following concerns regarding the: • Evidence used to inform authorized indications for AstraZeneca vaccine • Paucity of evidence available to the committee to review Covishield and to provide guidance on its use in Canada.	
4.	**Discussion on AstraZeneca** *For Discussion* (Matthew Tunis, PHAC)	Presenters provided an overview of the AstraZeneca COVID-19 vaccine [redacted] on effectiveness the AstraZeneca COVID-19 Vaccine, and emerging evidence on the efficacy of the AstraZeneca COVID-19 against variants of concern. NACI members deliberated on the age recommendation for the AstraZeneca	Members reached consensus to maintain the current recommendations as it is until evidence about Covishield is presented. Members agreed, in response to F/P/T feedback, to replace "benefits" and "risks"

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		COVID-19 vaccine and were supportive of maintaining the current recommendations for use in individuals 18 to 64 years of age. NACI members deliberated if the current NACI viral vector vaccine recommendations should be maintained as only an AstraZeneca COVID-19 vaccine recommendation or a more general ChAdOx1 recommendation so as to include the Covishield vaccine. Various members raised concerns regarding: [redacted] As Covishield vaccine is anticipated to be authorized, a decision was required. Members requested more time to deliberate on evidence, rationale, implications, and strategies for recommendation. In order to facilitate a more evidence-informed discussion, committee members requested that the NACI Secretariat present an assessment on the immunogenicity Robert Pless from BRDD agreed to investigate any historical precedence for a similar vaccine authorization, in order to provide more context. Member discussed the possibility of adding an addendum for the Covishield vaccine.	in NACI recommendation 1, b, i to: b. In the context of limited vaccine supply, ChAdOx1 COVID-19 vaccine may be offered to individuals 18 to 64 years without contraindications if: i. the advantages of earlier vaccination outweigh the limitations of vaccinating with a less efficacious vaccine;
February 25, 2021			
-	**Welcome and Introductions** *For Information / Approval* [redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. [redacted] informed the committee this was her last meeting as a NACI voting member as she is joining the Public Health Agency of Canada. The NACI Chair thanked [redacted] for her contributions to NACI over the course of her membership.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
4.	**Discussion on AstraZeneca Continued** *For Discussion* (April Killikelly, PHAC)	The committee was informed by the NACI Chair that as part of the authorization process both the AstraZeneca and Covishield COVID-19 vaccines will be deemed comparable by Health Canada. As result, members deliberated if / how to incorporate Covishield into NACI's Recommendations on the Use of COVID-19 vaccine. Members agreed to leave the statement with only AstraZeneca COVID-19 vaccine and review possible inclusion of the Covishield vaccine until after it is authorized and the product monograph is available. Presentation on *Immune bridging Serum Institute of India and AstraZeneca COVID-19 vaccines* covered: • Current global authorizations • High level immunogenicity and safety data • Clinical trial characteristics.	
5.	**Modeling data on COVID-19 vaccine intervals versus introduction of new vaccine** *For Information* (Austin Nam, PHAC)	The presenter provided preliminary results from the NACI compartmental model comparing the impact of extending dose intervals versus not extending for an mRNA vaccine campaign with/ without AZ. The key findings are below: • Benefits (i.e., reductions in infections, hospitalizations and deaths) are realized in extended dose strategies by 12 months, but not by 6 months. Most benefits are seen with a 12-week mRNA interval • Benefits of extended dose strategies are increased at a population level with the addition of AZ. The addition of AZ allows for faster access to doses for all. However, AZ may be harmful to the 55-64 year-old subgroup (i.e., increase hospitalizations and deaths), using the currently available phase 3 data. This occurs because in the vaccine roll-out, 55-64 yo would receive AZ instead of the more efficacious mRNA vaccine (VE data from RCTs). Preliminary results are sensitive to assumptions of VE against infection. Preliminary results did not appear sensitive to magnitude of waning or to time to waning. External models from the multi-model comparison broadly suggest similar support for extending dose intervals.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		The Allocation & Sequencing unit commented that a 24-week mRNA interval would not be needed given the anticipated supply to Canada. NACI members asked about mixed schedules (i.e., using mRNA vaccine as the second dose among those who received AZ as a first dose) and if complacency was included within the models (addressed at assumptions of 70% and 80% coverage).	
6.	**Intervals for mRNA COVID-19 vaccines and on COVID-19 vaccine program** *For Information* (Matthew Tunis, PHAC)	The presenter provided an overview of the: • proposed policy question; • triggers for NACI guidance; • current NACI interval recommendations; • FPT and international interval recommendations; • clinical efficacy, effectiveness summary & immunogenicity; • EEFA analysis; • proposed interval recommendations. Members deliberated the proposed recommendations and following considerations: • providing a clear and well-defined figure for the extended interval is supportive to immunization programming; • variants of concern and a potential third wave of COVID-19 call for a recommendation based on current limited evidence and expert opinion, • impact of extending the timing of the second dose to 3 to 4 months on cell-mediated immunity required for ongoing protection; • exclusion of specific groups from the extended interval recommendations considering the limited VE data from BC and QC for HCW and LTCF residents; • 80% VE could be more nuanced as a range was presented in the VE estimates from QC and BC • An extended interval would allow for increased vaccination coverage with a limited supply, supporting population-level health protection during a global pandemic.	• Members (13) supported extending the interval between COVID-19 mRNA vaccines to 4 months, while also acknowledging this is based on expert opinion and limited evidence. This commitment to monitor the evidence and adjust recommendations as further evidence emerges should be clearly stated. • Members agreed to have the extended interval apply at the population level and to avoid specifying any groups that could be exempt from the extended interval recommendations. • Members affirmed that NACI is still recommending a **two**-dose schedule but simply with an extended interval between doses. • Removing the "attempt to" and "preferably" language in favor of a more definitive position. • To reword the rationale sections to include a range of vaccine effectiveness findings in order to be more representative of data reported to date

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
7.	**Vaccine schedule for previously infected** *For Discussion* (Kelsey Young & April Killikelly, PHAC)	This item postponed due to insufficient time for discussion	Vaccine schedule for previously infected will be discussed at the next NACI meeting.
8.	**Next Steps** *For Information* (Matthew Tunis, NACI Executive Secretary)	The NACI Executive Secretary provided updates on anticipated web publishing of the *NACI Recommendations on the Use of COVID-19 vaccines (AstraZeneca)*. An outline of the critical path for drafting, committee review, approvals, and availability of embargoed NACI recommendations for extended interval between mRNA COVID-19 vaccine doses was also discussed. These recommendations will be published at different time points. NACI committee and liaisons members were reminded they cannot correspond with the public on behalf of NACI. Should members receive correspondence about their work on NACI, it is to be forwarded directly to the NACI inbox for response from PHAC. Support is available for those receiving persistent emails and members were asked to report these situations to the secretariat straightaway. Members discussed if NACI's mandate could include guidance on immunization errors and minimum intervals in an effort to support conservation of doses. While historically NACI has not commented, these issues are raised often. These topics could fall within NACI's mandate and other NITAGs have provided this type of guidance. The NACI secretariat indicated willingness to prepare information and discuss with the committee at a future meeting. Members were invited to attend the NACI VSWG meeting on March 2, 2021 to hear safety data directly from manufacturer regarding Janssen COVID-19 vaccine. The next NACI meeting is on March 10, 2021 from 10:30 AM to 12:30 PM EST to review evidence for the vaccine schedule for previously infected and Janssen COVID-19 vaccine. Presentation and current Janssen data is available for members on CNPHI.	NACI Secretariat will draft the extended interval guidance for committee review and approval via email.

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, June 1, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** • **Membership Updates** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared. The NACI Chair provided the following updates: • Starting in June 2021, new liaisons representatives will be added to the NACI membership. These representatives are from the following organizations: the Canadian Pharmacist Association, Canadian Indigenous Nurses Association and Indigenous Physician Association of Canada. • NACI recently issued a call out for membership for the upcoming vacancy in Public Health and Preventive Medicine expertise that will be left once [redacted] become NACI Chair on June 10, 2021. [redacted] will be joining NACI as the new Public Health and Preventive Medicine expert. • NACI Secretariat will be issuing a call out for membership for a pediatric infectious disease specialist as well as an immunologist with expertise in infectious disease and vaccine research instead of replacing the pharmacology expertise position. • The NACI Influenza Working Group (IWG) Chair need 2-3 voting and liaison members to join. For any interest, NACI secretariat should be contacted	• Agenda for June 1, 2021 reviewed and approved.
2.	**Health Canada Regulatory Status Update** *For Information* (Presenter: Celia Lourenco)	The presenter from Health Canada (HC) provided a brief regulatory status update on COVID-19 vaccines. • Health Canada is schedule for an upcoming meeting with Moderna to discuss exact timelines on the availability of the clinical data on adolescent (expect in early June) and details on manufacturing sites from the US supply which will increase the number of Moderna doses coming to Canada. • HC has authorized the extension of the expiry date of AstraZeneca doses (previously May 31, 2021).	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• HC is waiting for additional information from the Emergent facility regarding Janssen vaccines distribution. Health Canada will continue to monitor information quality and safety and once the information is available, it will be share with the NACI secretariat. • Medicago phase 2 clinical trials information was received recently, and the clinical data will be share with the NACI secretariat. • A meeting with Sanofi will be held this week to discuss their potential submission to Health Canada (potentially filed in July). They did announce that their phase 3 clinical trial global study was initiated last week.	
3.	**PHAC Safety Update** *For Information* (Presenter: Susanna Ogunnaike-Cooke, Natalia Abrahams)	The presenter from PHAC Vaccine Safety section provided an update on GBS and Myocarditis in Canada following COVID-19 vaccination, and share the PHAC communication strategy. Items covered by the presentation included: • Proposed Canadian case surveillance definition of Myocarditis, according to Brighton Collaboration criteria. • Summary of current Myocarditis cases counts following COVID-19 vaccination. • Observed and expected cases by age group and sex for each vaccine. • The communication planning which will consist of sending messaging through a communiqué to the provincial and territorial health authorities, Chiefs Medical Officers of Health, heath practitioners and the general public will be indicating that PHAC and Health Canada are monitoring international reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines. Based on reports received, Canada is not seeing higher rates than would be expected in the general population. Health Canada and PHAC are aware of these cases and will continue to monitor closely. Health practitioners should include myocarditis in their evaluation in case of patient presenting with symptoms such as shortness of breath, chest pain or rapid heart palpitations. • Summary of GBS cases following COVID-19 vaccination in Canada and outcomes at time of reporting.	• [redacted] (NACI voting member) to officially present CANVAS surveillance data (signal detection data related to myocarditis) at a future NACI meeting. • Health Canada confirmed that they will request more information from the international partners regarding planned rigorous studies and will inform NACI secretariat for any update.

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, June 1, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
4.	**Updates and discussion on myocarditis following mRNA COVID-19 vaccine** *For Information* (Presenters: Joseline Zafack, Matthew Tunis)	The NACI Executive Secretariat provided an update regarding NACI role on addressing myocarditis events following mRNA COVID-19 vaccine. • Whether NACI should integrate myocarditis events thought the Recommendations on the use of COVID-19 vaccines statement. • Israel have been examining possible link between cases of myocarditis and the COVID-19 vaccines. On June 7th, Israel will hold a confidential meeting to present their findings and a small NACI delegation will attend (Chair, Co-Chair, VSWG Chair) and PHAC officials. On June 10th, their findings will be presented to the general public. NACI secretariat is in contact with CDC and Israel to present on their myocarditis cases data in an upcoming NACI meeting. Following this update, it was agreed that the next NACI statement should contain the information on myocarditis events following mRNA COVID-19 vaccination to be consistent given that previous NACI statements included VITT in their recommendations. Emphasis should be made that to-date, myocarditis cases observed are less than expected in Canada and that NACI acknowledged and monitor the situation carefully and continue to recommend the vaccine. The NACI Secretariat provided an evidence update on Myocarditis following mRNA COVID-19 vaccines. Items covered by this presentation included: • A brief update on Pfizer safety data (Pfizer Summary Monthly Safety Report) [redacted] • All cases were reported by number of doses, delay of onset, sex, age and outcome (most of the cases were from Israel and mostly male). An age-stratified observed to expected ratio analyses of Myocarditis and Pericarditis was also presented. • Data limitations due to age of vaccine roll-out prioritization in older age group were briefly discussed. • Review of national and international recommendations/statements	• NACI Chair requested that NACI Secretariat contact [redacted] to elaborate a protocol for myocarditis investigation which could be share through the Canadian Immunization Research Network (CIRN). • The NACI secretariat will work closely with PHAC Vaccine Safety section and will proposed best approach to integrate myocarditis events in the statement.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
5.	**Presentation: Information needs for COVID-19 Vaccines in Pediatric Populations** For Information (Presenter: Nicole Forbes)	The presenters from the NACI secretariat and PHAC provided an update on the following: • Vaccine rollout in the pediatric population – Overview of safety signals in adolescent and young adults based on international reports of myocarditis/pericarditis; vaccination coverage for adolescents across Canada; and a brief summary of ongoing pediatric vaccine trials by Pfizer-BioNTech, Moderna, Novavax. • Vaccine supply update – Vaccine availability for the pediatric population will not be a concern based on estimates that second dose coverage for 90% of the population (12 years and older) will be achieved in the last week of July with the current supply. This will allow for increased availability of vaccines for the pediatric population (11 years and under) to be 100% vaccinated by early August. • Update on the burden of COVID-19 disease in pediatric populations based on data from the PHAC Surveillance and Epidemiology Division. • Overview of the anticipated policy questions, proposed options for the recommendations, and EEFA/ethical considerations from the Public Health Ethics Consultative Group Report (from May 2021). • Proposed modelling scenarios to inform NACI guidance on the use of COVID-19 vaccines in pediatric populations.	N/A
	Discussion: Information needs for COVID-19 Vaccines in Pediatric Populations *For Discussion* All	Following the presentation on the proposed modelling approaches for the pediatric population, there was discussion with NACI members on whether there is a need for modelling in that age group. The stringent public health measures that have been enforced which may have impacted younger age groups was mainly for the protection of vulnerable groups. When a large majority of adults (12 years of age and older) and vulnerable populations are vaccinated, these strict measures may not be necessary for children who largely do not present with underlying medical conditions. Based on this assumption, it may not be necessary to have modelling for this age group. Some members raised that the persistence of variants that are resistant to vaccine and have high transmission rates during the fall warrants modelling a variant scenario, as this would mostly affect children. Vaccinating children will allow for individual/population-level protection and the prevention of outbreaks caused by a large proportion of unvaccinated individuals. It was noted that many outbreaks in the school and daycare	• The NACI Secretariat will following up with PHAC Vaccine Safety unit on Canadian Data that can be shared with the Canadian Pediatric Society (CPS) to include in the CPS COVID-19 Statement which will address myocarditis. • The NACI Secretariat will follow up with the COVID-

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		setting are due to household contacts and that the modelling may not be of benefit if the source of infection (teachers, household contacts) is no longer a concern owing to vaccine uptake. Two out of 15 voting NACI members voted in favor of an analysis/modelling for variants of concern.	19 Immunization Task Force (CITF) for their group to present their modelling which includes vaccination rollout and the impacts of vaccinating children.

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, June 15, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter [redacted]	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for June 15, 2021 reviewed and approved.
2.	**Health Canada Regulatory Status Update** *For Information* (Presenters: Celia Lourenco, Kelly Robinson)	The presenter from Health Canada (HC) provided a brief regulatory status and safety update on COVID-19 vaccines. Items covered by this presentation included: • HC has authorized supply of Moderna vaccine. • [redacted] • HC will publish an article in InfoWatch to increase awareness and stimulate reporting on Myocarditis. • HC is closely monitoring reports of myocarditis/pericarditis and capillary leak syndrome (CLS) following AZ vaccination. • HC is considering updating warnings on the label for the COVID-19 vaccines to include a contraindication on Myocarditis. This update will be based on the current evidence and in collaboration with the manufacturer.	N/A
3.	**PHAC Safety Update** *For Information* (Presenter: Susanna Ogunnaike-Cooke)	The presenter from PHAC Vaccine Safety section provided an update on thrombosis with thrombocytopenia syndrome (TTS), myocarditis/pericarditis, Guillain-Barré Syndrome (GBS) and capillary leak syndrome (CLS) in Canada following COVID-19 vaccination. Items covered by this presentation included: • Summary of cases of TTS, myocarditis/pericarditis and GBS and base on reports received, PHAC is not seeing higher rates than would normally be expected.	• [redacted] NACI Chair, provided an update following the recent NACI recommendations who will be present to SAC on June 15, 2021. Going forward, urgent requests for NACI members review will be assigned at least 24 hours in advance in order to ensure enough time for inputs from all members.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• PHAC is closely monitoring national and international reports of adverse events following vaccination with COVID-19 mRNA vaccines. • CSL events reported are very rare and monitored closely.	
4.	**Presentation: Update on Myocarditis/Pericarditis following mRNA COVID-19 vaccines** *For Information* (Presenter: Joseline Zafack)	The NACI Secretariat provided an evidence update on myocarditis/pericarditis following mRNA COVID-19 vaccines. Items covered by this presentation included: • Data from Moderna safety report and clinical trial in adults, US and Europe (EMA and UK) data on myocarditis/pericarditis following mRNA COVID-19 vaccines. Following the presentation, clarification was provided on: • The proportion of cases among 12-15 years old in UK is not currently known. It is expected that the proportion is small given limited number of doses administered at this stage in this age group. • Members shared concerns on limited clinical data. The ACIP meeting on June 18, 2020 will provide further data. • NACI member provided additional context regarding the EMA data on Moderna vaccine – It is not largely used in Europe and the lower count of myocarditis cases in the younger age group is expected given that vaccine was recently authorized in this age group.	N/A
5.	**Presentation: Framing NACI guidance on mRNA COVID-19 Vaccines for Adolescents** For Information (Presenter: Nicole Forbes)	The presenters from the NACI Secretariat provided an update on NACI's current and forthcoming guidance on mRNA COVID-19 vaccines for adolescents. Items covered by this presentation included: • International and domestic recommendations on Pfizer vaccination for adolescents (≥12 years of age). • Update COVID-19 vaccine coverage and burden of COVID-19 disease in adolescents.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Brief overview of current evidence suggesting indirect protection from COVID-19 vaccine. • Review of Moderna's Phase 3 clinical trial efficacy findings in study participants 12 to <18 years of age, including an overview of efficacy estimates against symptomatic/asymptomatic SARS-CoV-2 infection and against overall COVID-19 infection irrespective of symptoms. • Review of Moderna's Phase 3 clinical trial immunogenicity and safety findings in study participants 12 to <18 years of age, including an overview of local/systemic reactions, serious adverse events (AE) and other AEs of interest. • EEFA considerations from the May 2021 Public Health Ethics Consultative Group report. • Considerations and options for NACI guidance on the use of mRNA vaccines in high risk/non-high risk adolescents (12 to 17 years of age).	
6.	**Discussion: mRNA COVID-19 Vaccines for Adolescents and Myocarditis/Pericarditis** *For Discussion/Decision* All	Following the presentation, members discussed the following: [redacted]	• 0 out of 13 NACI voting members did not agree with issuing a recommendation prior to the ACIP meeting scheduled for June 18, 2021. • 7 out of 13 NACI voting members voted in favor of scheduling a meeting during the weekend (June 19 or June 20, 2021) to discuss the recommendations, following a review of data presented at the ACIP meeting while the remaining 7 members voted to schedule the meeting for Monday, June 21, 2021.

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, June 15, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted]	
6.	**Next Steps** *For Information* (Presenter: [redacted])	The next NACI meeting is on June 21, 2021, from 15:00 – 16:30 EST, following the Advisory Committee on Immunization Practices (ACIP) meeting where there will be data presented on myocarditis and discussions on COVID-19 mRNA benefit-risk analyses pertaining to the adolescent population.	• NACI Chair shared that the date for the next NACI meeting is tentative and will be based on the discussions held at the ACIP meeting. Following the review of data, if there is a need for urgent action from the committee, the meeting may be rescheduled on the weekend.

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National Advisory Committee on Immunization

Record of Decisions

Monday, June 21, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for June 21, 2021 reviewed and approved.
2.	**Discussion: Global Considerations for Vaccine Recommendations** *For Information / Discussion* (Presenter: Matthew Tunis)	The presenter from NACI Secretariat provided an update on a global equity perspective regarding the use of COVID-19 vaccine in adolescents. Items covered by this presentation included: • Terms of Reference state that NACI is responsible for providing vaccine recommendations based on the burden of disease and public health needs in Canada. • Historically a comparable situation arose with HPV vaccine when it was in short supply. SAGE urged countries to not move forward with vaccination for boys and men until countries with low vaccine supply could first vaccine girls and women at elevated risk. At that time, NACI deemed international vaccine supply to be out of their scope. • Questions arose as to whether a NACI advice would influence vaccine allocation decisions at the federal level and if Canada could logistically reallocate pediatric and adolescent doses to other countries. • In the interests of time, discussion on this issue was deferred until after the presentation on NACI guidance on mRNA COVID-19 vaccines for adolescents. • If members feel strongly NACI could comment on the global supply issue through a one-page document for publication.	
3.	**Presentation: Framing NACI guidance on mRNA COVID-19 vaccines for**	The presenter from the NACI Secretariat provided an update on the framing of the NACI guidance on mRNA COVID-19 vaccines for adolescents.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	adolescents *For Information* (Presenter: Nicole Forbes)	Items covered by this presentation included: • International guidance on mRNA COVID-19 vaccines for adolescents. • Current COVID-19 vaccination programs for adolescents across provinces and territories and for adolescents in Indigenous communities. • Update on COVID-19 vaccine coverage in adolescents. • Emerging evidence on indirect protection from COVID-19 in non-vaccinated populations when community vaccination rate is high. • Myocarditis/pericarditis update using surveillance from PHAC, the US, France, Germany, Norway, UK, Australia, New Zealand, Switzerland, and Israel. • Current NACI guidance and recommendations for mRNA COVID-19 vaccines and the use of Pfizer BioNTech in adolescents. • Potential approaches to NACI recommendations for the use of mRNA COVID-19 vaccines in adolescents; for general population, for those at high risk of severe outcomes, by gender or by vaccine product. Following the presentation, clarification was provided on: • Whether the international guidance on the use of mRNA vaccines in adolescents was based on vaccine supply, existing evidence, or other factors. The presenter clarified that STIKO seemed to be based on supply. However, the basis for other international recommendations would need to be reviewed and made available to NACI members in the future.	
4.	**Discussion: mRNA COVID-19 Vaccines for Adolescents** *For Discussion / Decision* All	There was discussion with NACI members on whether the committee should continue to recommend mRNA vaccines for the adolescent population, in the context of the emerging safety signal of myocarditis/pericarditis observed in younger age groups. • Excluding the considerations around the potential safety signal of myocarditis, members were unanimously in favour of maintaining the current NACI recommendation for adolescent vaccination.	• In view of anticipated data on myocarditis from ACIP on June 23, 2021, members agreed to table discussion on mRNA COVID-19 vaccines for adolescents until after the above meeting.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• The ACIP meeting on June 23, 2021 (postponed from June 18, 2021) will discuss the most recent data on myocarditis/pericarditis obtained from VAERS/VSD and the severity and clinical course of confirmed cases. • Overall, members were supportive of delaying decisions to update the recommendation for the adolescent age group following the ACIP meeting on June 23, 2021. • Members indicated that the emerging safety signal of myocarditis may extend beyond those 12 – 17 years of age. If so, NACI recommendations may need to extend beyond adolescents. • Member noted that according to Lopez Bernal et al., 2021 one dose of vaccine is not enough to protect against variants. • Members recognized the importance of vaccinating youth from a population health perspective and discussed the impact that a delayed second dose may have on the adolescent population, specifically in the context of increasing cases of variants of concern (VOC), notably, the delta variant. • A remote and isolated Indigenous community in Ontario (ON) has seen outbreaks despite a 75% 2nd dose vaccine coverage rate in adults. It appears that more young people experienced COVID-19 infection as a result. • A member confirmed that ON has 26 AEFIs reports consisting of myocarditis and pericarditis cases, 7 cases under 18 years of age, 2 that required hospitalization. Reporting lags may be a potential contributing factor to the lower national case counts. • Request for PHAC to provide the proportion of children 12 – 17 years of age with underlying conditions that were admitted to hospital for myocarditis following vaccination. • Other considerations include current prioritization of second doses on schedule to First Nations and Inuit adolescents in some jurisdictions and whether the emerging safety signal is product specific. • Health Canada (HC) is maintaining ongoing discussions with international regulators regarding emerging safety signals. HC anticipates that the outcomes of the June 23, 2021 ACIP meeting will	• NACI Secretariat to follow up internally to to provide the proportion of children 12 – 17 years of age with underlying conditions that were admitted to hospital for myocarditis following vaccination.

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		determine whether labelling modifications would be warranted prior to HC's authorization of the Moderna vaccine.	
6.	**Next Steps** *For Information* (Presenter: [redacted]	NACI Chair summarized that: • Excluding the potential safety signal, members were unanimously in favour of continuing with the current adolescent vaccine recommendations • The committee will review the more granular data and risk-benefit analysis presented at the June 23, 2021 ACIP meeting. • The group will reconvene later this week to discuss the above and make a decision regarding the adolescent recommendations. • HC will also be invited to share their perspective on the ACIP data. NACI Chair proposed a new approach to expedite the review process; the adolescent statement (excluding recommendations) will be circulated to members for comment. The next NACI meeting is on June 22, 2021 from 11:00 – 11:45 EST.	• NACI Secretariat to circulate current adolescent statement to members for comment.

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, June 22, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for June 22, 2021, reviewed and approved.
2.	**Presentation: Public Health England (PHE) Dose 2 Effectiveness Data Update** *For Information* (Presenter: [redacted]	The presenter from Public Health England (PHE) provided updates on effectiveness and immunogenicity data following the first and second dose of Pfizer and AstraZeneca (AZ) COVID-19 vaccine. [redacted]	• N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
3.	**Q&A** *For Discussion* All	[redacted]	• N/A
4.	**In-camera Discussion** *For Discussion* All	There was discussion with NACI members on the following points: • Importance of providing explicit recommendations regarding intervals for mixed schedules in the absence of a product monograph. • Future interval recommendations will need to balance the need for protection against the delta variant and the emerging evidence that longer intervals between doses may be more effective. • Members also voiced concerns about shortened intervals in the light of increased mRNA vaccine supply and political pressure to vaccinate as quickly as possible. • One member stated that NACI should not recommend the dose intervals to be less than 6 weeks. However, it was noted that authorized intervals in Canada are less than 6 weeks, and this discrepancy may pose various challenges.	• Vice-Chair will follow up with provincial health authority regarding research of healthcare worker (HCW) populations who might have received doses at a shorter interval. • Executive Secretary will ask if any entities in Canada have been able to do a relevant powered analysis at this time and bring the information back to NACI.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Health Canada commented that any changes to the authorized interval would hinge on the submission of additional data from the sponsor. • Existence of Canadian research looking at VE among HCPs who received mRNA vaccines as per the product monograph. Members unaware of any current studies, however this type of research would be very useful.	
6.	**Next Steps** For Information (Presenter: Matthew Tunis)	The NACI Executive Secretary shared the following next steps: • Myocarditis and a discussion about intervals are on the agenda for next NACI meeting. • There is interest at the CMOH level in understanding the dose intervals and NACI's subsequent recommendations. • In terms of forward workplan, intervals are slated to be addressed in July. • Results from the Com-CoV 1 study are scheduled to be presented on June 29, 2021. The next NACI meeting is on June 24, 2021, from 11:30 – 13:00 EST.	• NACI secretariat to follow up with PHE to inquire if / when Dose 2 VE data will be published.

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National Advisory Committee on Immunization

Record of Decisions

Wednesday, June 9, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared. Kim Elmslie and Dr. Theresa Tam shared words of gratitude to [redacted] on behalf of PHAC. They shared their appreciation of [redacted] integrity, expertise, professionalism and dedication as NACI Chair.	• Agenda for June 9, 2021 reviewed and approved.
2.	**Presentation: Epidemiological impact of adult COVID-19 vaccination program on adolescents and children in Israel** *For Information* (Presenter: [redacted])	The presenter from the Israel Ministry of Health provided an update on vaccination program in Israel and observed cases of myocarditis following Pfizer COVID-19 vaccination. [redacted]	N/A
	Q & A *For Discussion* All	The presenter provided the following clarifications in response to questions from members and attendees:	N/A

Approved by NACI Executive Secretary June 16, 2021

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted]	
3.	**Discussion on Myocarditis Recommendation** *For Discussion / Decision*	Due to time constraints, the discussion on Myocarditis recommendations will be held at the next NACI meeting on June 15, 2021, from 11:00 – 12:30 EST.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
4.	**ACIP Co-Administration Recommendation Update** *For Information* (Presenter: [redacted])	The presenters from Centres for Disease Control (CDC) provided an update on ACIP decisions regarding the co-administration of COVID-19 vaccines with other vaccines. [redacted]	N/A
5.	**Health Canada Regulatory Status Update** *For Information* (Presenter: Celia Lourenco)	The presenter from Health Canada (HC) provided updates on COVID-19 vaccine reviews and post-market surveillance. Items covered by this presentation included: • HC received Moderna's adolescent data and is conducting an expedited review which is expected to be complete by end of June. • [redacted] • HC continues to monitor the myocarditis situation and has recently completed reviewing Pfizer's monthly safety summary review which included an update on myocarditis and will be shared with NACI. • An EMA PRAC meeting to discuss myocarditis following COVID-19 vaccination and other key issues is forthcoming.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• HC plans on releasing an InfoWatch article on myocarditis in Canada to create awareness and stimulate reporting of any adverse events following COVID-19 vaccination. Following the presentation, clarification was provided on: [redacted]	
6.	**Introduction of New NACI Member and Liaisons** *For Information* (Presenter: [redacted])	The NACI Chair provided an update on the new NACI voting member and liaison members. The following new members were welcomed to the committee: • New NACI voting member: [redacted] • New Liaison members: [redacted]	N/A
7.	**Presentation: Co-Administration of COVID Vaccines with Other Vaccines** *For Information* (Presenter: Eva Wong, Angela Sinilaite)	The presenters from NACI Secretariat provided an update on COVID-19 vaccines and concurrent administration with other vaccines. It was noted that decisions to be made on the practice of co-administration would be based on expert opinion, given the limited body of evidence supporting or advising against this practice. Items covered by this presentation included: • Policy question, triggers for updated guidance, the proposed approach and decision point for consideration. • NACI's current recommendation on co-administration of COVID-19 vaccines with other vaccines (live or inactivated) • An overview of international and domestic (BC, QC) recommendations, recommendations from professional organizations, current evidence on the topic, forthcoming trials evaluating simultaneous administration of vaccines, anticipated benefits/harms associated with co-administration of COVID-19 vaccines with other vaccines, and EEFA considerations.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	Discussion on NACI Recommendation on Co-administration of COVID Vaccines with Other Vaccines *For Discussion/Decision* All	Several members raised concerns about challenges that may arise related to AEFI monitoring if NACI moves forward with recommending simultaneous administration of vaccines. Given the emerging safety signals associated with COVID-19 vaccines, it would be prudent to wait for data to become available on the safety of this practice, which will likely come in the late summer or fall. It was also noted that a large majority of Canadians would have completed their vaccination series with a COVID-19 vaccine by the end of the summer, which is prior to the implementation of the flu vaccination campaign. Additionally, there may be challenges related to immune interference and risk of increased vaccine hesitancy if the cause of an adverse event cannot be attributed to a particular vaccine. Some members raised that although there is a lack of data on co-administration of COVID-19 vaccines with other vaccines, the committee should consider a recommendation against routine co-administration and take into account special circumstances in which the guidance should be permissive to the simultaneous administration of vaccines. It was also suggested to consider shortening the interval if the advantages of vaccination outweigh the risk and possibly aligning the waiting period before receiving a COVID-19 vaccine and after administration of other vaccines (e.g., waiting for 7 days before receiving a dose of a COVID-19 after receiving a non-COVID-19 vaccine and waiting for 7 days after a COVID-19 to receive another vaccine). Members who were supportive of administering COVID-19 vaccines with other vaccines stressed the need for guidance on this issue, seeing as planning for the flu season has already begun. Although there are concerns related to AEFI follow-up, there is extensive experience with most routine non-COVID-19 vaccines that will allow health care providers to differentiate between common side effects of routine immunizations from adverse effects associated with COVID-19 vaccines. It was also noted that concurrent administration of multiple vaccines with the COVID-19 vaccine would allow for the opportunity to make individuals up to date with important routine immunizations, particularly individuals living in remote/isolated areas and families who may not return for subsequent doses to complete their immunization series.	• 6 out of 12 NACI voting members voted against COVID-19 vaccines administered simultaneously with other vaccines. • 10 out of 12 NACI voting members voted in favor of a recommendation advising against routine administration of COVID-19 vaccines with other vaccines. • NACI will not change its current guidance on the interval between administration of a COVID-19 vaccine following a non-COVID-19 vaccine and the interval between administration of a non-COVID-19 vaccine following a COVID-19 vaccine. The recommendation will be permissive for exceptional circumstances and will be based on expert opinion. The secretariat will circulate the additions to be made to reflect this decision to voting and non-voting NACI members for their input.

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Wednesday, June 9, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
8.	**Discussion on Vaccine Interchangeability Next Steps** *For Discussion* (Presenter: [redacted])	The presenter from the NACI secretariat shared additional evidence to inform NACI recommendations on Interchangeability. Items covered by this presentation included: • Summary of the immunogenicity (Barros-Martins, Hillus et al. Groβ et al.) and reactogenicity (Groβ et al.) findings from three new additional heterologous vaccine studies. • Updates on globally reported rates of VITT / TTS and myocarditis Following the presentation, clarification was provided on: • No additional cases of VITT have been reported in Canada after a second dose of AZ / Covishield vaccine • [redacted] • Janssen vaccine does not need to be include in the recommendations for interchangeability, as it is a single dose series. The committee deliberated on: • [redacted]	[redacted]
9.	**Next Steps** *For Information* (Presenter: Matthew Tunis)	NACI Executive Secretary shared that [redacted] is scheduled to present results of the Com-CoV study on June 29, 2021. Study protocol includes comparative assays for original SARS-CoV-2, it is being investigated if other VOCs may be analyzed. Matthew Tuins, Erin Henry, Gina Charos and [redacted] all expressed thanks on behalf of themselves, PHAC and all Canadians for the hard work and dedication of NACI Chair, [redacted] The next NACI meeting is on June 15, 2021 from 11:00 – 12:30 EST.	

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March 10, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
March 10, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* [redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared. Moving forward NACI meetings will be scheduled on a weekly basis to address ongoing stakeholder requests for the committee. These scheduled meetings may be shortened or cancelled if not required. Finally, in September of 2020 NACI approved draft economic process, which outlined when and how NACI would incorporate economic evidence into vaccine recommendations. The public consultation on this process is is now available on the NACI webpage, under methods and processes. The purpose of the consultation is to get feedback on clarity, information gaps and whether the guidance documents achieve their purpose. Committee Members and Liaison Representatives were invited share this opportunity with their networks and encourage participation. The results of this public consultation will have significant impact on shaping NACI's health economics processes moving forward.	• Agenda for March 10, 2021 reviewed and approved.
2.	**2.0. AstraZeneca age cap: vaccine effectiveness and recommendation review** *For Information* (NACI Secretariat)	The presenter provided an overview of recently published evidence from three non-peer reviewed pre-prints publications on AstraZeneca vaccine effectiveness in the UK population. Items covered by this presentation included: • Comparisons of age and use recommendations from Regulatory Agencies, NITAGs and P/Ts for AstraZeneca COVID-19 vaccine (AZ) • Critical appraisal of the three studies (Vasileiou, E et al, Bernal JL et al and Hyams et al) which assessed effectiveness of the AZ vaccine. During the question period, the presenter provided clarifications on:	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Studies assessing the VE against the South African variant were not included as the population of interest is above 65 years of age. Variant specific data among hospitalization events in the PHE studies were included and the most prevalent variant was B.1.1.7.	
	2.1. Discussion *For Discussion / Decision* (All)	Following the presentation, NACI members deliberated on the proposed recommendations and discussed the following: • A member raised concerns regarding the timing to make this recommendation and noted the scrutiny on NACI following the previous AstraZeneca recommendations. • Concerns on the lack of available clinical trial evidence to support making a strong NACI recommendation were raised, and a member stated that publications from US clinical studies will be released by mid-April and a decision is expected at the current moment. • Concerns on the methodological issues affecting the reliability of the results from the pre-print by Vasileiou et. al, 2021 were raised and a member suggested to mention Vasileiou et al and the concerns raised with the appendix in the statement. • Members stated that the results from the Bernal JI et al, 2021 and Hyams et al, 2021, pre-prints studies were compelling and to include a summary of these studies in the statement appendix. • Members recommended to maintain a preferential recommendation for the mRNA vaccines to ensure their availability for high-risk groups and 65 years and older population. • Members recommended to lift the age restriction to 18+ for AZ vaccine and instead to include clarification on which key populations should preferentially use mRNA vaccine. • A member raised concern that ease of storage and handling in the rational to use AstraZeneca vaccine should not prompt efficacy. • [redacted]	1) NACI members came to consensus to expand the recommended age range to 18+ 2) NACI members came to a consensus to maintain the preferential recommendation, while continuing to monitor and update the recommendations as new evidence emerges. 3) NACI members came to a consensus to lift the age cap and more specifically indicate which key populations from the NACI Guidance on the prioritization of initial doses of COVID-19 vaccine should be prioritized. 4) The NACI secretariat will draft another version of this recommendation and will send it to the members for approval.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Most members stated that communication is critical at this stage. • A member stated that in the recommendation the population most at risk should be clearly defined. • For consideration, a member stated that there is a major supply of mRNA vaccines and lower supply of AstraZeneca vaccine. • A member stated that when NACI made the previous AstraZeneca recommendation, the PHE data were not published, and modelling data were used to make the decision. • Members mentioned the importance to give a strong recommendation and to reframe the current recommendation to increase immunization and reduce deaths and hospitalization.	
3.	**3.0. Vaccination in those with previous COVID-19 infection: Review of rationale and proposed recommendation** *For Information* (NACI Secretariat)	The presenter shared a presentation on vaccination of individuals who have had previously PCR-confirmed SARS-CoV-2 infection. Items covered by presentation included: • triggers for the guidance, • policy questions including the number of doses to be administered to individuals with previous SARS-CoV-2 infection and timing of vaccination, • NACI's current recommendations on vaccination of individuals with previous infection, • international recommendations on the dosing interval and number of doses for individuals with previous infection, • summary of EEFA considerations, and • NACI's proposed discretionary recommendation on the use of COVID-19 vaccines in individuals with previous PCR-confirmed SARS-CoV-2 infection. The presenter commented the arbitrary age limit of 70 years in the proposed NACI recommendation and clarified it is based on NACI's guidance on the prioritization of initial doses which recommends offering initial doses to adults ≥ 70 years in stage 1.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		NACI chair shared an update on the recruitment of HCWs with previous infection for vaccination and highlighted polyclonal expansion and cell-mediated immunity was observed based on a report of findings.	
	3.1. Discussion *For Discussion / Decision* (All)	Following the presentation, NACI member deliberated on the proposed recommendations and discussed the following: • A member raised a concern regarding the Ct cut-off value and noted that individuals who were PCR-positive with high CT values were often seronegative and expressed interest in knowing what proportion of total PCR-positive cases those individuals comprise. • The lack of available evidence to support or challenge NACI's recommendations. A NACI member stated that assessing emerging safety and reactogenicity data following the first and second dose in individuals with previous SARS-Cov-2 infection is warranted prior to making the recommendation. NACI chair noted that reconciliation of RCT data may not be possible, however, data evaluating vaccine safety in those previously infected and those previously naïve after receiving the first dose of COVID-19 vaccine will be shared at a NACI meeting scheduled later this month. • Members discussed whether the proposed recommendation is motivated by safety concerns or dose-sparing strategies as this may influence members' stance on the recommendation. • Members suggested considering residents living in congregate care settings where achieving indirect immunity should also be a targeted outcome. • A few members were supportive of the one dose recommendation excluding individuals in high-risk groups.	• Proposed recommendation will not be actioned until additional safety data is presented at the next NACI meeting to facilitate an evidence-informed discussion.
4.	**4.0. Presentation: Janssen Data Updates and proposed recommendations** *For Information* (NACI Secretariat)	Item was deferred until March 16, 2021 NACI Meeting.	

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National Advisory Committee on Immunization
Record of Decisions
March 10, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
	4.1. Discussion on proposed Janssen recommendations *For Information* (All)	Item was deferred until March 16, 2021 NACI Meeting.	
5.	**Next Steps** *For Information* (Matthew Tunis, NACI Executive Secretary)	Janssen Data Updates and proposed recommendations will be presented next meeting. Vaccination in those with previous COVID-19 infection will be discussed later in March. AstraZeneca age cap: vaccine effectiveness and recommendation will be circulated to NACI this week for final approval. The next NACI meeting is scheduled for March 16, 2021 from 10:00 AM to 11:30 AM EST.	N/A

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National Advisory Committee on Immunization

Record of Decisions

Wednesday, March 24 & Thursday, March 25, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
March 24, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. One member submitted a potential conflict of interest (COI) which was reviewed as per process, and deemed not to be a COI. Previous committee member [redacted] To eschew the appearance of COI, consultative roles (paid or unpaid) with pharmaceutical companies are not permitted while on NACI. Members were invited to declare any new interests related to proposed meeting topics. Other than noted above, no additional conflicts of interest were declared.	• Agenda for March 24 & 25, 2021 reviewed and approved.
2.	**2.1. Presentation: Updated VE for dose 1 in UK** *For Information* (Presenter: [redacted])	The presenter from Public Health England (PHE) provided an update on one dose vaccine effectiveness (VE) of the Pfizer BioNTech and AstraZeneca COVID-19 vaccines. [redacted]	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted]	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	2.2. Presentation: Updated VE for dose 1 in QC *For Information* (Presenter: [redacted]	The presenter from the Institut national de santé publique du Québec (INSPQ) provided an update on surveillance-based assessment of the effectiveness of a single dose of COVID-19 vaccine in HCW's and LTCF residents in Québec. Items covered by this presentation included: • Surveillance data on vaccine effectiveness, incidence comparison between those vaccinated and unvaccinated in HCWs and limitations were discussed. • Results suggested that to date, a single dose of mRNA vaccine provides a good protection in HCWs. • Population surveillance data show substantial vaccine impact in targeted groups in Québec. • Data suggested onset of vaccine protection around 14 days after the first dose for HCWs and later in LTCF residents. Following the presentation, clarification was provided on: • The death and hospitalisation data from the outbreak in a Québec long-term health care facility. • The follow-up period for the screening method for crude VE analysis was 10 weeks due to data availability. • Lack of information available on the presence of VOCs in the long-term health care facility during the outbreak. • Confirmation that the VE data presented were for 1 dose. • HCWs and LTCF individuals with previous PCR+ infection prior the 1st dose were excluded from the analysis. • Limitations may include that only PCR+ cases were excluded, and some cases would have been missed. However, inclusion or exclusion of PCR+ individuals in the analysis does not largely affect the results.	
3.	**3.0. Presentation: Safety on AstraZeneca - EMA Review** *For Information*	The presenters provided an update on the recent AstraZeneca COVID-19 vaccine safety signal (risk of thrombosis and thrombocytopenia). Items covered by this presentation included:	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	Presenters: Joseline Zafack and Bryna Warshawsky (PHAC)	• The EMA statement dated March 18 2021 • Information from the Paul-Erlich Institut in Germany • At this point a causal relationship cannot be confirmed or ruled out. • Review of thrombotic events for mRNA, COVISHIELD and Janssen COVID-19 vaccines • Mechanism of action for spontaneous heparin-induced thrombocytopenia (S.H.I.T.) including client advice, diagnosis and treatment • Recommendations from Regulatory Agencies, NITAGs and P/Ts • Implications for Canada	
	3.1. Discussion: Safety of AstraZeneca *For Discussion* (All)	Following the presentation, there was discussion with NACI members on how to move forward with this information: • HC participant stated that HC is poised to approve and post updates to the Product Monographs for AZ and COVISHIELD [redacted] • Nova Scotia has already put out a statement to HCPs and changed their consent forms. • Quebec met on the subject and will be issuing a statement soon. • It has been confirmed that the issue is not related to specific lots and Germany had ruled out previous or current SARS CoV-2 infection in most of their cases. • Members discussed whether to introduce a restriction on age for the AZ recommendation (allowing use only for older adults), while considering that spontaneous HIT may be underreported in older individuals (detection bias). • A few members suggested that the lack of safety signals being identified in the elderly population does not reflect a detection bias in the older populations, as HIT is a rare condition which may require hospitalization where it is unlikely to go undetected. • NACI members agreed that this safety signal information should be added to the COVID-19 vaccine statement and also shared at F/P/T tables.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• There is a meeting planned on Saturday March 27 with thrombosis experts from McMaster University and Germany to discuss this issue further.	
March 25, 2021			
-	**Welcome – Day 2** *For Information* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone.	
4.	**4.0. Presentation: Janssen Recommendations** *For Information* (Presenter: NACI Secretariat Staff)	The presenter highlighted key issues for discussion and provided an evidence summary to inform proposed changes to recommendations. Items covered by this presentation included: • Current NACI recommendations and potential changes for consideration. • A summary of evidence comparing the differences between vaccines. • Results of a survey distributed to members ranking the importance of various outcomes for COVID-19 vaccine program decision-making. • Summary of key evidence on efficacy and effectiveness outcomes for the four authorized vaccines against symptomatic disease, hospitalization, death, asymptomatic infection, and variants of concern. • Summary of evidence from Canadian surveys on vaccine acceptability and safety. • Proposed changes to the NACI recommendations for discussion. This includes areas of revisions from the NACI statement that was circulated, and suggested additions based on the AstraZeneca safety signals identified through passive surveillance programs.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	4.1. Discussion: Janssen Recommendation *For Decision* (All)	Following the presentation, the committee discussed the following: • Maintaining the preferential recommendation for mRNA vaccines - The 12 out of 13 of the members were supportive of maintaining the preferential recommendation for mRNA vaccines and to provide supplementary information on individual vaccines (including the risk-benefit assessment) elsewhere (e.g. below in the supporting bullets and / or the management option table). - One member stated their preference for keeping the preferential recommendation for the use of the mRNA vaccines in groups at highest risk of disease and exposure. • Separating the two viral vector vaccines in the recommendation - Given the amount of data currently available on the differences between AZ and Janssen vaccines, members were agreeable to distinguish between viral vector vaccines. - Members identified that maintaining simplicity in the main recommendation and including the specific details in the management options table will reduce potential confusion as the implementation of proposed recommendations will differ across provinces and territories based on regional epidemiology. - Members expressed strong inclination for highlighting the safety signals associated with the AstraZeneca vaccine in the recommendation for the purpose of maintaining transparency and public confidence. • Inclusion of the Janssen vaccine in the preferential recommendation - A member proposed the option of having a preferential recommendation for mRNA vaccines and the Janssen vaccine, excluding the AstraZeneca vaccine given the potential safety signals. However, concerns were raised about the impact this would have on overall vaccine acceptability. • A survey will be circulated to voting members in order to reach a consensus on the following proposed recommendations: - Retain NACI's strong recommendation for a complete vaccine series with mRNA or viral vector vaccine without a preferential recommendation [redacted]	Members will be required to complete the survey indicating their vote before 6 P.M. (EST) Thursday, March 26, 2021.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		- Maintain the preferential recommendation for mRNA and group the viral vector vaccines together. - Make a preferential recommendation for mRNA and Janssen vaccine.	
5.	**5.0. Presentation: Intervals Statement** *For Information* (Presenter: Bryna Warshawsky)	The presenter from PHAC provided an update on the newly available evidence which would help to address whether there should be any exceptions to the upcoming extended intervals statement. Items covered by this presentation included: • Currently available various new studies (conducted in different countries and settings) with data on vaccine immunogenicity and/or vaccine effectiveness (VE) for one dose and two doses of COVID vaccines among special populations (i.e. immunosuppressed / cancer patients, older adults, long-term care facility residents, frontline healthcare workers)(overall low certainty of evidence). • General considerations about VE for one-dose mRNA vaccines vs. two-dose mRNA vaccines vs. viral vector vaccines; reiterating the potential advantages and limitations of the extending the interval; and the interaction between the timing of national vaccine rollout and the extended interval. • CIC survey findings on implementing exceptions to extended interval. • Draft revised wording to the current NACI recommendation on the exception(s) to the extended interval. • For Discussion: At this time, should NACI comment on exceptions for vaccination with an extended interval (up to 4 months) for any particular group (e.g. long-term care facility residents, older adults, immunosuppressed, immunocompromised etc.)?	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	5.1. Discussion: Intervals *For Decision* (All)	Discussion following the presentation covered topics such as: • One dose in LTCFs seems to still offer enough protection. • Exceptions to the extended interval, may be more feasible in hospital settings than in the general community; distinction between those settings should be considered. • Suggestions to add some wording about the importance of maintaining precautions after vaccination until public health recommendations change. • Member suggested staying clear of framing in context of 'outbreak response' as not currently addressed in NACI guidance. The committee deliberated on the following two options: • Option 1: NACI should maintain the current recommendation on extended interval and continue to monitor the evidence, given that evidence certainty is low and insufficient at this time to make an exception to the extended interval. - Members noted the challenges that once exceptions are made for certain groups, more will follow possibly making 'exceptions' irrelevant. - Exceptions based on the low certainty evidence available today, does not mean that all 'exceptions' have been captured. There is currently an inequity in the groups for which data can be easily gathered to inform decisions (i.e. those in tertiary care settings can be easily studied by researchers vs. community living individuals with Downs syndrome, for example). • Option 2: NACI makes exceptions (i.e. 4-6 weeks between COVID-19 vaccines) for those with solid organ transplants and hematological malignancies. - If selecting option 2 may also want to include the very elderly/frail given that this group shows the same decline in immune response and are at even higher risk than those two proposed groups. - It was noted that immunogenicity evidence ≠ protection - It may be problematic to lump cancer patients and other immunocompromised patients together given that the risk of severe outcomes might be quite different between groups.	• NACI secretariat will make proposed updates to the extended intervals statement and carefully revise the wording to both reflect the available evidence while allowing P/Ts programming flexibility. • The committee voted 8 to 7 to maintain the current recommendation without exceptions (Option 1). As per NACI ToRs, 2/3 quorum is required for something to pass. Therefore an updated recommendation will be distributed electronically for another vote.

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		- It was noted that maintaining an extended interval for cancer patients and other immunocompromised patients would render them susceptible to COVID and its outcomes. - It was suggested that an exception to the extended interval for patients could be made for those with: solid organ transplants, hematological malignancies, and multiple sclerosis, given that the immunosuppressive medications they may be taking would cause them to not respond optimally to vaccines. Therefore, these patients may need two doses to stimulate a sufficient immune response (and some evidence does show that two doses stimulated greater immune response. The committee reached the following consensus: • The committee voted 8 to 7 to maintain the current recommendation without exceptions (Option 1). • Chair suggested that the concerns of the members who voted against Option 1 and the summary of evidence from the presentation today should be included in a Management Options table to inform provinces/territories (PTs) policies and acknowledge that there is data regarding differences in immunogenicity, but that the strength of evidence regarding effectiveness is uncertain. • Some PT's have existing policies exceptions to an extended interval. Wording for the extended intervals statement will allow some flexibility for the PTs based on their local/regional situation. • The Chairs and Vice Chair feel that the following must be clear: 1. NACI is not asking PTs to wait for 4 months, but NACI is making the recommendation allowing PTs to extend the interval up to 4 months during times of vaccine scarcity. 2. NACI suggests that PTs review in real time vaccination of priority groups. Once through everyone with first dose, then go back and start with those at the top of the priority list for dose one and offer them a second dose, after the other groups have all been vaccinated with the first dose (i.e. do not wait 4 months for no reason if the other groups have all been vaccinated with the first dose).	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
6.	**Next Steps** *For Information* (Presenter: NACI Secretariat Staff)	NACI Executive Secretary shared that the Janssen statement is planned to be web-published on April 9, 2021. The extended interval statement will be web-published on April 1, 2021. The next NACI meeting is on April 1, 2021 from 14:30 – 16:00 EST.	N/A

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, March 30, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
March 30, 2021			
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics, no conflicts of interest were declared.	• Agenda for March 30, 2021 reviewed and approved.
2.	**Presentation: Intervals Statement** For Discussion (Presenter: Bryna Warshawsky)	The presenter from PHAC provided an update on vaccine effectiveness (VE) data derived from the NACI extended dose intervals statement. Several studies continue to emerge from PHE, Israel, US, Denmark and the data is ever evolving. When appraising these international studies, it was suggested to view them in the context of their respective immunization programs as some countries (US and Israel) are not using the extended intervals as are the UK and Quebec. The presenter noted that the UK data will be our best source of data for that reason. Items covered by this presentation included: • Effectiveness data against symptomatic disease from the UK, Israel, and Canada. • Data on the effectiveness against asymptomatic infection in the US and Israel (Dagan). There were methodological issues identified in the Dagan paper. • PCR positive SARS-CoV-2: this data looks at vaccination status and test results irrespective of the presence of symptoms. The SIREN study was identified as the most reliable study as positive HCW were screened out and results continued to demonstrate 72% effectiveness. • Data on effectiveness against hospitalizations and from the UK, Scotland, and Israel • Studies evaluating effectiveness in long-term care from British Columbia, Quebec, Denmark, US, and the UK	• NACI and HCID members are to review and submit comments on NACI's extended intervals statement that has been distributed for appraisal. • PHAC will update modelling to reflect the lower VE estimates for symptomatic disease. This modelling will go into the statement before publication.

Approved by NACI chair: April 26, 2021

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Two-dose effectiveness data from Israel which are closely aligned with efficacy data. The data has also demonstrated effectiveness against asymptomatic infection. Following the presentation on effectiveness data, the following points were discussed among NACI members and meeting participants: • Proposal to include the effectiveness estimates presented today in a revised model, given that one/two-dose effectiveness, hospitalization data are now available. • A member noted a study from Scotland which showed a reduction in the rate of infection/transmission in household members of health care workers vaccinated with a single-dose of the Pfizer vaccine. However, questions were raised regarding the study's findings, as it is not known if the household members were previously infected. • The presenter of the modelling data stated there will be revisions made to the model given the new point estimates, which will include effectiveness against hospitalization and death. It is not expected that there will be a significant difference in the model following the information provided during today's presentation. • A member noted the need for a discretionary recommendation for some special populations, namely, elderly and immunocompromised persons. The committee voted in favor of putting a caveat on the current recommendation stating provinces/territories can use the recommendation as needed based on their local epidemiology.	

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National Advisory Committee on Immunization
Record of Decisions
Tuesday, March 30, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
3.	**Discussion: AstraZeneca safety status and next steps, implications for Janssen update** *For Discussion* (Presenter: [redacted]	The NACI Chair provided an update on the AstraZeneca safety signal status and next steps, and PHAC staff members discussed the implications for Janssen recommendations. Discussion following the presentation covered topics such as: • How to position Janssen (also a viral-vector vaccine) in consideration of the safety signal (VIPIT) with AstraZeneca vaccine. • Several options were presented, however, the Committee felt strongly that because the evidence was constantly evolving on the safety signal, that it would be premature to publish Janssen recommendations (as the vaccine is not yet available in Canada). • Approximately 3.2M doses of Janssen vaccine have been administered in the USA since the beginning of March (mostly in younger populations), however it would be too early to detect any safety signals. No phase 4 data available yet. The committee deliberated on: • A vote was taken as to whether to continue with developing the Janssen recommendations or to delay this discussion until there is more information on VIPIT and Canada is closer to receiving a Janssen vaccine supply. • 12 of 14 members voted in favor of putting a hold on the Janssen COVID-19 vaccine recommendations (all 14 voting members were present at the virtual meeting). The committee reached the following consensus: • To hold off on finalizing and publishing the Janssen vaccine recommendations until more information is available on VIPIT and Janssen are available. • To further discuss the VIPIT safety signal at the April 13th meeting following the submission of a benefit/risk assessment of AstraZeneca COVID-19 vaccine to Health Canada (expected the week prior).	• NACI Executive Secretary is to communicate with PHAC Senior Management that NACI has voted against providing Janssen vaccine recommendations for next week as planned, in light of safety issues. • As all the Janssen content (minus recommendations) are already drafted into the statement, NACI Secretariat will remove all the Janssen content and publish a statement with the evidence updates (i.e., ARCHE data, DART data, etc.).

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, March 30, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
4.	**Next Steps** *For Information* (Presenter: [redacted])	NACI Executive Secretary shared an update regarding a discussion held with AstraZeneca today. [redacted] A call of interest was made for NACI members who are interested in representing the committee in future media technical briefings. The next NACI meeting is on April 1, 2021 from 14:30 – 16:00 EST.	N/A

Approved by NACI chair: April 26, 2021

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, May 18, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted]	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for May 18, 2021 reviewed and approved.
2.	**Presentation: Media Training** *For Information* (Presenter: Louise Payette)	The presenter from Health Canada (HC) provided a brief overview on media relations and shared some practical advice to consider when communicating with the media; including how to approach requests for interviews, how to frame responses, and practices to avoid during interviews. As discussed at a previous NACI meeting, PHAC will be appointing spokespersons from the agency who will be responsible for media communications on behalf of NACI. HC will be responsible for negotiating the terms of the interview, recording the interview for validation of text, and follow up questions from the media.	N/A
3.	**3.0 Presentation: Adverse Events Update – Vaccine Safety** *For Information* (Presenter: Susanna Ogunnaike-Cooke)	Natalia Abraham from the PHAC Vaccine Safety Section provided an update on adverse events related to COVID-19 vaccines. Items covered by this presentation included: • The Canadian interim case definition for vaccine-induced immune thrombotic thrombocytopenia (VITT) which was approved by SAC on May 9th 2021. • Update on thrombosis with thrombocytopenia cases following COVISHIELD/AstraZeneca vaccination in Canada • Update on myocarditis cases in Canada following Pfizer vaccination. Following the presentation, clarification was provided on: • The PHAC case definition for VITT. • The comparability of Canada's safety surveillance data with internationally authorities.	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	3.1 Q&A: Adverse Events Update – Vaccine Safety *For Discussion/Decision* All	There was discussion with NACI members on: • The Brighton Collaboration does not yet have a case definition for myocarditis • There is no VITT safety signal with non-viral vector COVID vaccines • Thrombosis Canada is the best source for information related to screening.	• The PHAC safety section is to stratify the incidence estimates by 1st and 2nd doses for the TTS data and share with NACI. • The PHAC safety section is to update NACI on the safety surveillance data on Bell's palsy and Guillain-Barre Syndrome (GBS) at an upcoming meeting.
4.	**Health Canada Update: Myocarditis Internationally** *For Information* (Presenters: Kelly Robinson, Celia Lourenco)	Kelly Robinson from Health Canada provided an update on myocarditis internationally. Items covered by this update included: • Pfizer is reviewing the myocarditis reports on an ongoing basis as it is being discussed by regulators worldwide. • HC aims to have a review of the Pfizer data to share with NACI. • The US FDA is reviewing cases of self-limiting myocarditis and noted it is premature to consider it a safety signal. Following the presentation, clarification was provided on: • How to communicate this information with the general public. They need to be aware that we the situation is being monitored and that there is currently no safety signal for myocarditis and mRNA vaccines in Canada. • HC may be publishing in InfoWatch to stimulate awareness and reporting of myocarditis cases in relation to COVID-19 vaccination.	N/A
5.	**5.0 Presentation: Vaccine Administration Errors** For Information	The presenter from PHAC provided an update on a document PHAC is developing that addresses management of vaccine administration errors (i.e. practices that differ from the recommendations provided in products monographs and by NACI). The recommendations provided in this guidance document are recommendations from PHAC, not NACI. The	N/A

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	(Presenter: Bryna Warshawsky)	main topics were presented to the group for their expert input on the issues being considered for the document. Items covered by this presentation included: • Overview of practices that are not recommended but considered acceptable if they occur. • Errors requiring manufacturer guidance such as storage/handling errors, or the use of expired product/non-recommended diluent. • International and domestic guidance on the following: administering the second dose of a COVID-19 vaccine earlier than the minimum interval; administering less than a full dose; over dilution; and the proposed recommendations and rationale for each scenario. • International guidance on mixing COVID-19 vaccine products. • Proposed recommendations addressing the administration of high or incomplete doses (less than a full dose)	
	5.1 Q&A: Vaccine Administration Errors *For Discussion* *All*	There was discussion with NACI members on the following: • Interval shorter than the minimum interval: the second dose of vaccine, which was administered too early, would be considered an invalid dose; however, dose timing would be determined based on the second dose since it has already been administered and is likely to have an immunogenic effect. • The guidance should indicate that the assessment of whether a full dose was administered is based on the provider's report as opposed to the vaccine recipient. A member noted that placing the responsibility of determining the validity of the dose on the immunizer might lead to unwarranted pressure. • Clarification regarding the rationale for a 42-day interval between the first and second dose of vaccine, if the first dose was less than a full dose and a repeat dose was not administered. A member noted that there is no evidence to support the 42-day interval, and suggested reframing the recommendation to state that the final dose can be given as close as possible to the manufacturer's authorized interval given that there is more data to inform this recommendation. • Highlighting that the potency of a vaccine is not affected 6 hours after dilution since the concern is related more to the sterility of the product.	• CATMAT will be consulted on whether they can address the issue of vaccine products not approved in Canada; however, input from both NACI and CATMAT would be necessary.

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National Advisory Committee on Immunization
Record of Decisions
Tuesday, May 18, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• Mixing vaccine products: members deliberated on whether the vaccination series should be considered complete (i.e., no additional doses required) if the second dose of vaccine is not authorized in Canada but listed for Emergency Use by WHO.	
6.	**Next Steps** *For Information* (Presenter: [redacted]	The next NACI meeting is on May 26, 2021 from 13:00 – 15:00 EST.	N/A

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National Advisory Committee on Immunization

Record of Decisions

Wednesday, May 26, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for May 26, 2021 reviewed and approved.
2.	**Presentation: Mixed schedules/ interchangeability update for AZ/mRNA** For Information (Presenter: Ramya Krishnan)	The presenter from the NACI Secretariat provided an update on NACI's COVID-19 vaccine interchangeability recommendations. Items covered by this presentation included: • Policy question triggered by P/T requests – Is the use of a heterologous prime-boost schedule for COVID-19 immunization in Canada (CA) acceptable/recommended? o The proposed approach for NACI is to issue a rapid response statement similar to the NACI adolescent statement. • International recommendations on the 2nd dose for individuals who had AZ for their 1st dose and results from the CIC survey on the use of AZ/Covishield for the 2nd dose. • NACI's current recommendations on interchangeability. • Potential benefits/harms of a heterologous/homologous schedules based on data from international studies and clinical trials. • Overview of UK and US data on the rate of VITT following AZ use. • Forthcoming data from the Com-COV study (UK) and Mosaic study (CA) that will help inform NACI's interchangeability recommendations. • Overview of ethics, equity, feasibility, and acceptability (EEFA) factors to be considered for the recommendation.	• N/A
3.	**Presentation: Update on heterologous COVID-19 vaccine schedule study, Spain (CombivacS study)**	The presenter [redacted] from The Carlos III Health Institute (ISCIII) in Madrid provided an update on the CombivacS phase 2 randomized, multicenter, adaptive trial to evaluate the safety and immunogenicity of *Comirnaty* (Pfizer BioNTech) in subjects that had received one dose of *Vaxzeveria* (Oxford-AstraZeneca).	• N/A

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National Advisory Committee on Immunization

Record of Decisions

Wednesday, May 26, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
	For Information (Presenter: [redacted]	[redacted]	
4.	**Health Canada Update: Regulatory Status** *For Information* (Presenter: Kelly Robinson)	The presenter from Health Canada provided a regulatory update on Pfizer, Moderna, AstraZeneca, Janssen, Novavax and Medicago COVID-19 vaccines. [redacted]	• Health Canada to inquire about communication plans re: myocarditis following mRNA vaccines and will

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted]	share findings with NACI Secretariat.
5.	**Discussion: NACI mixed-schedule / interchangeability recommendation** *For Discussion/Decision*	There was discussion with NACI members on: • Clarification that this will be a stand-alone rapid response statement based on expert opinion, with the current availability of limited data. The recommendations in this stand-alone statement will be incorporated into the next update to the base statement.	• NACI came to the **following consensus, pending email confirmation from members on the final wording:**

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
	All	• The challenge is that there is no comparator group (e.g. either a two dose AZ group or a two dose Pfizer group), except for historical data from RCTs; however, that comparison is not necessarily useful given the different assays that might have been used. Caution to NACI not to make any comparative statements given that there is no direct comparison data. Suggestion to only focus on recommendations about general immunogenicity, and address issue of uptake of second dose AZ vaccine. • The Oxford trial immunogenicity data will be available in mid-June. • It is quite possible for NACI to look at "fold increase" post-boost in immune responses (e.g. nAbs and EIA against trimeric spikes, RBDs, etc.). NACI may be able to make some expert-based opinion with that data; however, it should not attempt to make strong statements about superiority given the lack of exact correlates of protection. • Members agree that the humoral immunogenicity data from the CombivacS mixed schedule study is more similar to the two-dose mRNA regimen than to the two-dose AZ regimen, and that although the data from this study (e.g. cellular immunity, etc.) is difficult to interpret, there is still value in using it as one of the sources to inform NACI's expert opinion-based statement. The committee deliberated on the proposed recommendations drafted by the NACI Secretariat: • Members voted on the two proposed options (for mRNA). There was no consensus as some member felt one option was more flexible than the other, and vice versa. ○ **The Chair proposed, without opposition from members,** that NACI should leave the wording as it is pending confirmation that P/Ts have no concerns about the current wording. NACI can revisit these two proposed options in the future if necessary. • Members discussed the two proposed options (for AstraZeneca/COVISHIELD). The following suggestions were raised and considered: ○ NACI should highlight that some people would not be able to receive mRNA as a second dose (i.e. contraindication to mRNA or personal preference), instead of framing this as a simple choice. ○ NACI should only comment on the available data instead of making assumptions without seeing the full evidence given the relatively weak	○ *NACI recommends that a vaccine series started with the AstraZeneca/COVISHIELD vaccine may be completed with the Pfizer vaccine (or with an mRNA vaccine). This recommendation is made in light of:* ▪ *The risk of VITT following AstraZeneca/COVISHIELD* ▪ *The possibility of increased short term reactogenicity with a mixed schedule* ▪ *Emerging data on immunogenicity of a mixed schedule. The available data on mixed schedule is currently only with Pfizer, but NACI considers Pfizer and Moderna to be interchangeable.* • The final wording of the mixed schedule recommendation will be

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		evidence from the CombivacS study and the possibility that UK trial data may show contradicting results. However, some pointed out that in the interest of providing leadership/guidance, a decision will need to be made by NACI at this time even with only limited evidence. ○ NACI should frame the new recommendation as being prompted by/mainly motivated by the risk of VITT from any dose of AstraZeneca—given the unlikelihood that a mixed schedule will show decreased efficacy—highlighting that early data from UK and Spain show acceptable short-term safety of a mixed schedule. ○ Recommend that patients who have received AZ dose 1 should be given the opportunity to receive AZ dose 2 as long as there was informed consent. NACI will then be able to frame the mixed schedule recommendation as "two doses is better than 1 dose" while also offering freedom of choice for people who might be weighing the risk of VITT against the unknown efficacy of a mixed schedule. However, some members countered that NACI should provide as much guidance as possible without putting the burden of decision-making on the individual or the front-line clinician.	sent to the Executive on Thursday with a 24-hour review window; and to NACI members on Friday also with a 24-hour review window. • Executive Secretary will reach out to CombivacS study investigators to clarify what exactly NACI is allowed to cite in the draft stand-alone statement.
6.	**Next Steps** **For Information** **(Presenter: [redacted])**	NACI Chair [redacted] shared that [redacted] have officially been named by PHAC as incoming Chair and Vice-Chair, respectively. Both have accepted their appointed positions. The next NACI meeting is on June 1, 2021 from 11:00 – 12:30 EST.	N/A

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, May 4, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter [redacted]	The NACI Chair opened the meeting and welcomed everyone. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics. No new conflicts of interest were declared.	• Agenda for May 4, 2021 reviewed and approved.
2.	**Presentation: Heterologous COVID-19 vaccine schedule study** *For Information* (Presenter: [redacted]	The presenter from the University of Oxford, Oxford Vaccine Group provided an update on interim COM-COV data comparing the immunogenicity of the heterologous with homologous prime/boost schedules administered at a 4 week interval. Items covered by this presentation included: [redacted]	N/A

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National Advisory Committee on Immunization
Record of Decisions
Tuesday, May 4, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
3.	**3.0 Presentation: Recommendation on Mixed Vaccine Platforms** *For Information* (Presenters: Kelsey Young, Shainoor Ismail)	The presenter from the NACI secretariat provided an overview of the recommendations on mixed schedules for different COVID-19 vaccine platforms triggered by a request for expert opinion at the May 1, 2021 Special Advisory Committee for COVID-19 meeting. Items covered by this presentation included the following: • International recommendations on COVID-19 vaccine interchangeability/mixed schedule (based on expert opinion). • A brief overview of the rate of VITT after the second dose of AstraZeneca (AZ) • Vaccine supply update (mRNA and viral vector) • Current recommendations on the interchangeability of COVID-19 vaccines and proposed additions addressing what vaccine to offer individuals if the previous dose is not available, or if an individual has a history of VITT following AZ.	N/A
	3.1 Discussion *For Discussion/Decision* All	Following the presentation, there was discussion with NACI members on: • The need for clear language highlighting: 1) NACI's guidance on mixed schedule dosing is currently based on expert opinion due to limited evidence; 2) the permissive use of a mixed mRNA schedule in the recommendation; 3) the subsequent mRNA dose would be considered the second dose of the two-dose series when a mixed AZ and mRNA schedule is applied; 4) reactogenicity data and vaccine supply. • Clarification on whether the recommendation applies to individuals who do not meet the diagnostic criteria for VITT (i.e., no platelet function tests performed or negative test). Currently, the recommendation applies to individuals with confirmed PF4 antibody tests. • Members agreed on the need for clear messaging and that the overall recommendation must be framed broadly, as there are multiple scenarios that may arise which cannot be addressed individually; furthermore, Provinces/Territories (PTs) can apply the recommendations as they wish in their respective jurisdictions. It was also suggested to add a sentence stating there may be scenarios that may warrant the use of a mixed schedule (e.g., adverse events) and should have no impact on the validity of the schedule. • Delaying issuing recommendations further, as data emerges on mixed schedules, cannot be considered, as PTs will use up their supply of AZ in May. • Members deliberated on the addition of a sentence to the recommendation addressing mixed schedules generically, rather than referring to a specific vaccine.	• The members reached a consensus (13 out of 13) on maintaining a generic recommendation (without AZ).

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National Advisory Committee on Immunization
Record of Decisions
Tuesday, May 4, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
4.	**Presentation: Vaccine Safety on rate of VITT in Canada** *For Information* (Presenters: Susanna Ogunnaike-Cooke, Natalia Abraham)	The presenter from PHAC, Vaccine Safety provided an update regarding Thrombocytopenia with Thrombosis Syndrome (TTS) in Canada and covered the following items: • Proposed Canadian case surveillance definition of TTS, based on Brighten Collaboration and how it differs from VITT. Presenter shared plan for P/T validation and approval. • Summary of current TTS case counts (confirmed and under investigation) and national/international TTS rates • Potential projected national rates and background rates (pending cases under investigation) • It was noted that the TTS cases to date are more than the estimated background rate of thromboembolism with thrombocytopenia. Following the presentation, clarification was provided on: [redacted]	N/A
5.	**5.0 Presentation: Pregnancy/Breastfeeding, Immunocompromised and Autoimmune Populations** *For Information* (Presenters: Natalia Abraham, Ramya Krishnan, Shainoor Ismail)	The presenters from PHAC and the NACI secretariat provided an evidence update on vaccine use in pregnant/breastfeeding, autoimmune and immunocompromised persons; and the proposed recommendations for each group to consider for the forthcoming COVID-19 statement. Items covered by the Pregnancy/Breastfeeding presentation included: • An overview of the impact of COVID-19 on pregnancy outcomes, epidemiological data on the burden of COVID-19 in pregnant persons in Canada, immunogenicity and safety data for mRNA and viral vector vaccines in pregnant and breastfeeding persons and an environmental scan of international recommendations in pregnancy and breastfeeding Items covered by the Immunocompromised and Autoimmune Populations presentation included: • An overview of following: data from the ARCHE rapid review and Canadian surveillance on disease burden; an environmental scan of international recommendations on immunocompromised persons and persons with autoimmune conditions; and an evidence review on safety, vaccine effectiveness and immunogenicity in these populations	N/A

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National Advisory Committee on Immunization

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Tuesday, May 4, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
	5.1 Discussion: Pregnancy/Breastfeeding, Immunocompromised and Autoimmune Populations For Discussion/Decision All	There was discussion with NACI members on: • Changing the preferential recommendation for mRNA vaccines in pregnant persons from a discretionary to a strong recommendation. • Recommending that a viral vector COVID-19 vaccine may be offered only in the event a pregnant individual has an allergy to a component of an mRNA COVID-19 vaccine (discretionary). • The inclusion of the pregnant/breastfeeding recommendations in the main recommendations for the general population, that is a preferential recommendation for an mRNA COVID-19 vaccine and a permissive recommendation for viral vector COVID-19 vaccines (including informed consent about the risk of VITT and the limited evidence on the use of viral vector vaccines in this population). Following the presentation on the evidence update on immunocompromised persons and those with an autoimmune condition, it was decided that decisions on recommendations for these populations would be deferred to next week following a review of the evidence on extended intervals.	• 8 out of 13 members were in agreement with the proposed recommendations for pregnancy/breastfeeding. • 8 out of 13 members voted in favor of not offering viral vector vaccines to pregnant women unless there are contraindications (e.g., allergies). • All members voted in favor of removing the interval between series completion and COVID-19 vaccination. • There was consensus among NACI members to issue a preferential recommendation for mRNA vaccines and discretionary recommendation for viral vector vaccines in breastfeeding persons.
6.	**Next Steps** *For Information* (Presenter: Matthew Tunis)	NACI Executive Secretariat summarized the committee's decisions to move forward with expert opinion on interchangeability and move decision regarding recommendations for special populations (including addressing intervals) to another meeting during the week of May 10 to 14, 2021. The next NACI meeting is on May 11, 2021 from 11:00 – 1:30 EST. The committee will be presented with updated data on intervals by age, the new indications for adolescents.	N/A

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

June 2, 2021 | 11:00am-1:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Oliver Baclic, Bailey Beaudoin, Yung-En Chung, Leanne Coward, Kelly Farrah, Veronica Ferrante, Nicole Forbes, Anabel Gil, Christina Jensen, Anna Jirovec, Ramya Krishnan, Su Hyun Lim, Nima Mohamed, Austin Nam, Kaeli Ramotar, Natalie St. Pierre, Angela Sinilaite, Rob Stirling, Matthew Tunis, Man Wah Yeung, Eva Wong, Raphael Ximenes, Kelsey Young, Joseline Zafack (24)
	PHAC & HC Participants	Natalia Abraham, Helen Anyoti, Deborah Danoff, Kimberley Hutchings, Jhona Rose (HC), Amanda Shaw, Bryna Warshawsky (6)
	NACI Members	[redacted]
	HCID Working Group Members	[redacted]
	AstraZeneca Participants	[redacted]
Total in Attendance	50	

Agenda Item #1- Welcome and Introduction- Agenda & Declaration of Interests & Presentation

WG Chair welcomed working group members, PHAC participants, NACI Secretariat, NACI HCID WG, NACI Voting Members. The meeting agenda was approved as presented and no conflicts of interest were declared for this meeting. Presentation by NACI Secretariat followed.

Agenda Item #2- AstraZeneca Presentation

Presentation: [redacted]

Presented by: [redacted]

[redacted]

WITHHELD / RETENUE

Is(Are) exempted and/or excluded pursuant to section(s)
est(sont) exemptée(s) et/ou exclus en vertu de(s)(l')article(s)

20(1)(b)
Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains (b) financial, commercial, scientific or technical information that is confidential information supplied to a
Le responsable d'une institution fédérale est tenu, sous réserve des autres dispositions du présent article, de refuser la communication de documents contenant : b) des renseignements financiers, commerciaux, scientifiques ou techniques fournis à

20(1)(c)
Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains (c) information the disclosure of which could reasonably be expected to result in material financial loss or
Le responsable d'une institution fédérale est tenu, sous réserve des autres dispositions du présent article, de refuser la communication de documents contenant : c) des renseignements dont la divulgation risquerait vraisemblablement de causer des

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[redacted]

WG Chair thanked AstraZeneca for the presentation. AstraZeneca members left the meeting (11:40pm).

Agenda Item #3- Myocarditis Presentation

Presentation: Update on myocarditis following mRNA COVID-19 vaccines
Presented by: Joseline Zafack

NACI Secretariat briefly presented the Pfizer Summary Monthly Safety Report (April 1-29, 2021), the data from the press release of the Israeli Ministry of Health, and international recommendations/statements.

[redacted]

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[redacted]

Presentation: Update on myocarditis in Canada
Presented by: Natalia Abraham, PHAC Vaccine Surveillance Team

PHAC Vaccine Surveillance presented updated CAEFISS data.

Q&A:

1. Did any of the Canadian cases have myocarditis biopsy done?
   Answer: None of them had a biopsy done.

2. For the pericarditis cases, did any of them have pericardial fluid removed or analysed?
   Answer: None of the Canadian cases had invasive testing.

3. Regarding pregnancy, is it possible to ascertain pregnancy or post partum studies?
   Answer: There are fields for pregnancy and this is often collected in medical history. Post partum would be a more difficult to identify.

4. For the 21 total case reports, is there a breakdown by province?
   Answer: With low case counts, we try not specify location (Vaccine surveillance will provide location specified data to VSWG).

Adjournment

The WG Chair thanked the WG and participants for their time and contribution.

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NACI Vaccine Safety Working Group (VSWG):

COVID-19 Focus

RECORD OF DECISIONS

March 02, 2021 | 3:00am-4:00pm

Participants	**Working Group Chair**	[redacted]
	Working Group Members	[redacted]
	NACI Secretariat	Elissa Abrams, Oliver Baclic, Yung-En Chung, Leanne Coward, Pamela Doyon-Plourde, Kelly Farrah, Veronica Ferrante, Anabel Gil, Shainoor Ismail, Christina Jensen, Ramya Krishnan, Christine Mauviel, Nima Mohamed, Austin Nam, Stephie Pierre, Kaeli Ramotar, Caroline Rodriguez-Charette, Angela Sinilaite, Rob Stirling, Chantale Tremblay, Man Wah Yeung, Eva Wong, Raphael Ximenes, Joseline Zafack (24)
	PHAC & HC Participants	Helen Anyoti, Kristin Bennett, Kimberley Hutchings, Karin Johnson, Gila Metz (HC), Amanda Shaw, Bryna Warshawsky (7)
	NACI Members	[redacted]
	HCID Working Group Members	[redacted] Marina Salvadori, [redacted]
	Johnson & Johnson Participants	[redacted]
Total in Attendance	66	

Agenda Item #1- Welcome and Introduction- Agenda

WG Chair welcomed participants and Janssen members.

Action items: None

Agenda Item #2- [redacted]

Presented by: [redacted] Janssen Pharmaceutical Companies of Johnson & Johnson

[redacted]

WITHHELD / RETENUE

Is(Are) exempted and/or excluded pursuant to section(s)
est(sont) exemptée(s) et/ou exclus en vertu de(s)(l')article(s)

20(1)(b)
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WITHHELD / RETENUE

Is(Are) exempted and/or excluded pursuant to section(s)
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[redacted]

Agenda Item #3- Closing Remarks

WG Chair asked that any additional questions should be sent to the NACI secretariat for forwarding to Janssen. Members indicated that having Janssen present efficacy data may be of interest. NACI Vice-Chair proposed the HCID WG as venue. NACI Vice-Chair to follow up with NACI Executive Secretary to discuss if potentially feasible.

Adjournment

The WG Chair thanked the WG and participants for their time and contributions.

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FOR CONCURRENCE

21-107423-130

MEMORANDUM TO THE VICE PRESIDENT

Electronic Dissemination and Web Posting of the National Advisory Committee on Immunization (NACI) *Recommendations on the Use of COVID-19 Vaccines (VITT Evidence Update)*

SUMMARY

- NACI has updated their *Recommendations on the use of COVID-19 vaccines* (Appendix A) in response to reports of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) following vaccination with the AstraZeneca vaccine.
- NACI has reviewed materials from Health Canada's recent safety assessment, the mRNA vaccine availability, and epidemiological COVID-19 risk by age.
- NACI continues to preferentially recommend mRNA COVID-19 vaccines for individuals in the authorized age group without contraindications; however, in areas where COVID-19 activity is high or very high, vaccine-eligible adults who do not wish to wait for an mRNA vaccine may be offered the AstraZeneca vaccine if certain conditions, including a benefit-risk assessment, are met.
- This update provides provinces and territories with recommendations on how to optimize the use of the AstraZeneca vaccine in their jurisdictions to achieve the greatest population-level public health benefit.
- Your urgent concurrence for the electronic dissemination and web posting of this updated guidance is requested, in order to release this evidence update on the COVID-19 vaccines in Canada.

BACKGROUND:

Since COVID-19 vaccines were first authorised in Canada in December 2020, the National Advisory Committee on Immunization (NACI) has been providing evidence-informed *Recommendations on the Use of COVID-19 Vaccines* to help inform the ethical, effective and equitable rollout of COVID-19 vaccines in Canada, in the context of staggered vaccine authorization.

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Following post-licensure of the AstraZeneca COVID-19 vaccine, rare cases of serious blood clots with very low levels of platelets have been reported globally, including two confirmed cases in Canada as of April 17, 2021. This condition is being referred to as Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT).

On March 29, 2021, NACI recommended an immediate pause in the use of the AstraZeneca COVID-19 vaccine in individuals under 55 years of age in light of VITT. NACI made this recommendation out of an abundance of caution while investigations into the association of VITT with the AstraZeneca vaccine were conducted.

NACI held full committee meetings on April 13, 15, and 17, 2021, to formally review emerging evidence on VITT and to discuss updates to their recommendations. Updated recommendations were approved by NACI on April 17, 2021.

NACI's updated recommendations are informed by Health Canada's recent safety assessment; evidence and international guidance on VITT; the availability of alternative COVID-19 vaccines, and their characteristics (efficacy, effectiveness, safety), in Canada; the rapidly changing epidemiological conditions of COVID-19 in Canada, including the circulation of variants; and a comprehensive analysis of the implication on ethics, equity, feasibility and acceptability.

CONSIDERATIONS:

The updated recommendations are as follows:

NACI continues to preferentially recommend a complete series with an mRNA COVID-19 vaccine be offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered. (Strong NACI Recommendation)

NACI recommends that a complete series with the AstraZeneca COVID-19 vaccine may be offered to individuals without contraindications in select age ranges* in areas where COVID-19 activity is high or very high ONLY if the individual does not wish to wait for an mRNA vaccine AND ALL of the following conditions apply:

a) The benefit-risk analysis** determines that the benefit of earlier vaccination with the AstraZeneca COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
b) As part of benefit-risk analysis, the following is considered (in addition to other factors)**: The risk of severe outcomes of COVID-19 decreases with decreasing age. In age groups younger than 50 years of age, the benefit provided by offering AstraZeneca COVID-19 vaccine instead of waiting for an mRNA vaccine is not a certainty; AND
c) The benefits and relative risk** and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as other effective personal public health measures to

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mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND

d) There will be substantial delay to receive an mRNA vaccine.

Note: The AstraZeneca COVID-19 vaccine should not be offered in areas of very low, low, or moderate COVID-19 activity.

NACI has included the below decision tool to help identify in which ages ranges the AstraZeneca vaccine may be considered.

Local COVID-19 activity	Age range where the benefit of AstraZeneca COVID-19 vaccine may outweigh the risk
High (≥3 COVID-19 cases/ 10,000 per day)	50 years and older
Very High (≥6 COVID-19 cases/10,000 per day)	40 years and older

Provinces and territories can also refer to a Risk Assessment Framework for the use of the AstraZeneca vaccine included in NACI's updated statement. The benefit-risk analysis for who to consider offering the AstraZeneca vaccine to may vary between jurisdictions and individuals and will depend on:

- Local COVID-19 epidemic conditions;
- Local vaccine supply and characteristics of available vaccines;
- Logistical considerations;
- Risk of exacerbating health inequities;
- Access to diagnosis tools and treatment for COVID-19 or VITT;
- Risk of severe illness and death;
- Risk of exposure, including public health measures individuals can take to minimize their exposure; and
- Risk of Vaccination-Induced Immune Thrombotic Thrombocytopenia.

Health Canada ex officio members reviewed and commented on the plain language summary of NACI recommendations before NACI Chair approval.

COMMUNICATIONS IMPLICATIONS:

NACI's updated recommendation has significant implications for communications. Media lines have been developed to support public release of NACI guidance. The Chair and Vice-chair of NACI presented their updated recommendation to the Special Advisory Committee (SAC) on April 18, 2021. The updated statement will be distributed with PTs under embargo as soon as it is approved by PHAC on Monday April 19. Publication of the updated statement is planned for Tuesday, April 20, 2021, and will be supported by a technical briefing for media and associated web products.
It is likely that some jurisdictions will announce program changes before the NACI announcement.

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Key opinion leaders, including Chief Science Advisor, will be briefed by PHAC on Monday April 19 in advance of NACI publication.

NACI has also created a summary document to accompany the statement update.

RECOMMENDATIONS/CONCLUSION:
It is recommended that you indicate your concurrence to proceed with electronic dissemination and web publishing of the enclosed document by signing the "concur" block below.

_____
Gina Charos
Director General
Centre for Immunization Readiness

☐ do not concur
☐ concur

_____ _____
Kimberly Elmslie Date
Senior Vice-President
Immunization Programs

_____ _____
Howard Njoo MD, MHSc, FRCPC Date
Deputy Chief Public Health Officer and
Interim Vice-President
Infectious Disease Prevention and Control Branch

MECS# 21-107423-130

Contact: Erin Henry
Telephone: 613-222-6174

Attachments:
Appendix A – Recommendations on the Use of COVID-19 Vaccines

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FOR CONCURRENCE

21-108408-115

MEMORANDUM TO THE VICE PRESIDENT

Electronic Dissemination and Web Posting of the National Advisory Committee on Immunization *Recommendations on the Use of COVID-19 Vaccines (Janssen Update)*

SUMMARY

- NACI has updated their *Recommendations on the Use of COVID-19 Vaccines* (Appendix A) following Health Canada's authorization of Janssen's COVID-19 vaccine on March 5, 2021.
- NACI recommends the Janssen vaccine may be offered to individuals 30 years of age and older without contraindications, if the individual does not wish to wait for an mRNA vaccine and if the benefits outweigh the risks.
- NACI has also updated its recommendation for vaccination in pregnant individuals, preferentially recommending a complete vaccine series with an mRNA COVID-19 vaccine if the benefits outweigh the risks.
- In addition, NACI reaffirms that, until further evidence emerges, those previously infected with SARS-CoV-2 may be offered a complete series with a COVID-19 vaccine.
- Your urgent concurrence for the electronic dissemination and web posting of this updated guidance is requested, in order to release advice in advance of the arrival of the Janssen COVID-19 vaccine in Canada at the beginning of May 2021.

BACKGROUND:

Since the authorization of the first COVID-19 vaccine in Canada in December 2020, the National Advisory Committee on Immunization (NACI) has been providing evidence-informed *Recommendations on the Use of COVID-19 Vaccines* to help inform the ethical, effective and equitable rollout of COVID-19 vaccines in Canada, in the context of staggered authorization of vaccines.

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NACI's overarching recommendation on the use of COVID-19 vaccines has been updated to include guidance on the use of Johnson & Johnson's Janssen COVID-19 vaccine. The summary of evidence and rationale for this recommendation has been updated.

Health Canada authorized the Janssen COVID-19 vaccine for individuals 18 years of age and older on March 5, 2021. It is a single dose vaccine that can be stored and transported at refrigerated temperatures ranging from 2° to 8°C for at least three months.

NACI held full committee meetings on March 16, 25 and April 13, 26, 2021, to review the most up to date efficacy, effectiveness, immunogenicity and safety evidence of the Janssen COVID-19 vaccine. NACI's updated recommendations are also informed by Canada's rapidly changing COVID-19 epidemiology and public health principles of ethical decision-making, including equity, feasibility and acceptability.

Clinical trial data available to date demonstrate the Janssen vaccine is 67% efficacious across all age groups against moderate to severe symptomatic COVID-19 infection at least two weeks after receiving the vaccine. Preliminary evidence suggests vaccine offers protection against the B.1.351 variant of concern, first identified in South Africa, and the P.2 variant of interest, first identified in Brazil. There have been confirmed reports of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) after administration of the Janssen vaccine, as seen with the AstraZeneca vaccine. As of April 23, 2021, 15 cases have been confirmed following the administration of more than 8 million doses of the Janssen vaccine in the United States (US). The United States Advisory Committee on Immunization Practices, NACI's US equivalent, has concluded that the benefits of the Janssen vaccine outweigh the risks. Evidence on the efficacy, immunogenicity and safety of the Janssen vaccine has been added in a new appendix.

This update provides provinces and territories with recommendations on how to optimize the use of the Janssen vaccine in their jurisdictions to achieve the greatest population-level public health benefit.

Other key updates to NACI's *Recommendations on the Use of COVID-19 Vaccines* include:

- A preferential recommendation for the use of mRNA COVID-19 vaccines in pregnant individuals, if the benefits outweigh the risks. Additional information has been added to the summary of evidence and rationale for the pregnancy and breastfeeding recommendations.
- After reviewing the most up to date evidence, NACI continues to recommend a complete COVID-19 vaccine series to individuals previously infected with COVID-19.The summary of evidence and rationale has been updated for this recommendation.

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CONSIDERATIONS:

NACI's updated recommendations are as follows:

Overarching Recommendations

A complete series with an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) *should be* preferentially offered to individuals in the authorized age group without contraindications to the vaccine. If an mRNA vaccine is contraindicated, another authorized COVID-19 vaccine should be offered (Strong NACI Recommendation). NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide, the absence of any safety signals of concern and the acceptability of the vaccines by people in Canada. NACI notes that Canada has procured and is expecting enough mRNA vaccines to fully vaccinate the currently eligible Canadian population before fall 2021.

A complete series with viral vector COVID-19 vaccine (AstraZeneca, Janssen) may be offered to individuals 30 years of age and older without contraindications only if the individual prefers an earlier vaccine rather than wait for an mRNA vaccine AND all the following conditions apply (Discretionary NACI Recommendation):

a) The benefit-risk analysis* determines that the benefit of earlier vaccination with a viral vector COVID-19 vaccine outweighs the risk of COVID-19 while waiting for an mRNA COVID-19 vaccine; AND
b) The benefits and relative risk* and consequences of VITT and COVID-19 for the individual are clearly outlined, factoring in the anticipated waiting time to receive an mRNA vaccine as well as the availability of other effective personal public health measures to mitigate risk of COVID-19, and the individual makes an informed decision based on an understanding about these risks and benefits; AND
c) There will be substantial delay to receive an mRNA vaccine.

NACI recognizes that public health benefit-risk analyses for the use of the viral vector vaccines, including Janssen's vaccine, may vary between jurisdictions based on their unique circumstances. NACI notes that provinces and territories should adapt the age limit based on their local epidemiology. Health officials can refer to a Risk Assessment Tool for the use of the Janssen vaccine included in NACI's updated statement.

Pregnancy Recommendation

NACI recommends that a complete vaccine series with a COVID-19 vaccine (preferably with an mRNA vaccine) may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the evidence of the use of COVID-19 vaccines in this population (Discretionary NACI Recommendation).

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NACI preferentially recommends the use of mRNA vaccines (Pfizer-BioNTech, Moderna) in pregnant individuals due to the difficult and complex treatment of VITT in pregnant individuals, should it occur following the administration of a viral vector vaccine (AstraZeneca, Janssen). In addition, recently published data from a study in the United States have indicated no safety signals have been seen following the administration of the mRNA COVID-19 vaccines in pregnant individuals. The summary of evidence and rationale for the pregnancy and breastfeeding recommendations have been updated with additional information from Developmental and Reproductive Toxicity (DART) animal studies for Janssen COVID-19 vaccine. The evidence summary has also been updated to reflect current research on COVID-19 vaccination during pregnancy and breastfeeding.

Previously Confirmed COVID-19 Infection Recommendation

NACI continues to recommend that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection. (Discretionary NACI Recommendation)

NACI considered the most up to date evidence and data, including evidence from recent observational studies in previously infect individuals. In the absence of one-dose vaccine effectiveness data in previously infected individuals, particularly as it relates to variants of concern, NACI recommends individuals previously infected with SARS-CoV-2 continue to receive a complete vaccine series at the recommended intervals, regardless of the severity of their infection. The summary of evidence and rationale has been updated for this recommendation.

COMMUNICATIONS IMPLICATIONS:

This guidance has significant implications for communications. Publication of the statement is planned for Monday, May 3, 2021 and will be supported by a technical briefing for media. Media lines and a plain language summary have been developed to support public release of the guidance.

The NACI Chair and Vice Chair will present this update to the Special Advisor Committee (SAC) on Sunday, May 2, 2021. The updated statement will also be shared with PTs under embargo on May 2, 2021. The Chief Science Advisor and other key opinion leaders will be briefed by PHAC on Monday, May 3, 2021, in advance of publication.

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RECOMMENDATIONS/CONCLUSION:

It is recommended that you indicate your concurrence to proceed with electronic dissemination and web publishing of the enclosed document by signing the "concur" block below.

Gina Charos
Director General
Centre for Immunization Readiness

☐ do not concur
☐ concur

Kimberly Elmslie
Senior Vice-President
Immunization Programs
MECS# 21-106337-883

Date

Howard Njoo MD, MHSc, FRCPC
Deputy Chief Public Health Officer and
Interim Vice-President
Infectious Disease Prevention and Control Branch

Date

MECS# 21-108408-115
Contact: Erin Henry
Telephone: 613-222-6174

Attachments:
Appendix A – Recommendations on the Use of COVID-19 Vaccines
Appendix B – Summary of NACI recommendations May 3, 2021

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National Advisory Committee on Immunization
FINAL Record of Decisions
December 14 & 17, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
December 14, 2020				
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** For Information / Approval ([redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. Previously, [redacted] No other conflicts of interest were declared.	**Actions / Decisions** • Agenda for December 14, 2020 was approved.	
2.	**Presentation of clinical evidence for Moderna COVID-19 vaccine** For Discussion (Kelsey Young, Rob Sterling, April Killikelly & Ramya Krishnan, NACI Secretariat)	*NACI COVID-19 Vaccine Statement: Clinical Evidence* was presented by the NACI Secretariat for the Moderna COVID-19 vaccine including: current phase 1/2a/3 trial characteristics, vaccine efficacy, immunogenicity and safety evidence (see presentation for details). Timing regarding the anticipated regulatory decision for the Moderna COVID-19 vaccine was shared with the committee. The question and answer session covered the following topics: • Similarities and differences between Pfizer BioNTech and Moderna COVID-19 vaccines including: length of follow up, duration and differences in cellular immune response and comparability of results. It was noted that without a bridging standard, comparison of immunogenicity results would be difficult. • Data for the cumulative number of COVID-19 cases in the experimental and control groups starting on the day of	• NACI and HCID WG members to review meeting materials and updated statement in order to finalize recommendations on Thursday, December 17, 2020	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		administration of first dose has been requested from Moderna. • Clarification regarding number of events (pregnancies, deaths and anaphylaxis) in both vaccine and placebo study arms.		
3.	**Discussion of emerging policy/clinical questions** • **Extended interval between doses** • **Intervals around pregnancy** • **Autoimmune disorders** For Discussion (Shainoor Ismail, NACI Secretariat)	*NACI COVID-19 Vaccine: Emerging Policy Questions* was presented by Shainoor Ismail (see presentation for details). Objectives were to seek clarification form NACI regarding the following key questions: **Extended Interval Between Doses** • Based on a recent survey, members agreed that COVID-19 vaccines could be considered interchangeable as long as the vaccine platforms are the same. Preference would still be to use the same product if possible. • Members identified that it is important to clarify with PTs the reason NACI does not provide a defined maximum interval between doses. The intention was so people would not have to restart the series, and not because NACI is endorsing a one-dose schedule. • The current evidence clearly shows that a series is 2 doses, and there is not enough data at this time regarding the safety and efficacy of a single dose. The second dose might be critical given the trajectory of the immune response. • NACI's role is to lay out all the elements for consideration to allow the P/Ts to do their own risk benefit analysis regarding dosing, intervals and supply management.	• NACI and HCID WG members to review meeting materials and updated statement in order to finalize recommendations on Thursday, December 17, 2020 • EEFA framework to be used to frame considerations to inform PT risk management of vaccine supply	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		• Members urge that EEFA factors be carefully considered, and an EEFA framework be shared widely to support P/T decision making. **Intervals Around Pregnancy** Committee came to consensus to include wording as presented for intervals around pregnancy with the following changes: • Keeping the suggestion to delay pregnancy by at least 28 days post vaccination with a complete two dose series, while removing the rationale related to 'a full ovulation cycle.' • Removal of wording related to consistency between this interval and the recommendation to delay pregnancy after vaccination with the live MMR vaccine. **Autoimmune Conditions** • Consensus reached that immunosuppression and autoimmune conditions be separated under different headings as the rationales for the recommendations are different. • Sweeping recommendations will be difficult, as it is likely that not all autoimmune disorders will react to COVID-19 vaccines in the same way; therefore, it's best to allow HCPs to make that decision with their patients. **Next Steps**		

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		• NACI members will receive the base statement for review, and then will discuss and approve at the Thursday December 17, 2020 NACI meeting.		
December 17, 2020				
4.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** • **RODs from December 4&7, 2020** For Information / Approval ([redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics. No new conflict, since day 1 of this meeting was declared. No changes were required to the proposed agenda for Dec 17, 2020. If necessary, substantive changes to the RODs from December 4 & 7, 2020 should be sent to the NACI Secretariat.	• Substantive changes to RODs from RODs from December 4 & 7, 2020 should be sent to the NACI Secretariat. They will be reviewed by the NACI executive if required.	
5.	**Clinical evidence for Moderna COVID-19 vaccine – Update** For Discussion (Kelsey Young, NACI Secretariat)	Additional interim analyses of vaccine efficacy and new safety data from Phase 3 clinical trials for the Moderna COVID-19 Vaccine were presented. See presentation for details NACI discussed that these findings may increase interest surrounding the considerations of asymptomatic transmission potential. It was re-affirmed that the committee will need to be descriptive of the preliminary findings and clear that proof of reduction of asymptomatic transmission is not yet demonstrated.		

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National Advisory Committee on Immunization
FINAL Record of Decisions
December 14 & 17, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
6.	**COVID-19 Vaccine Recommendations – Moderna update** For Approval (Shainoor Ismail, NACI Secretariat)	*NACI Base Evergreen Statement: Recommendations on the use of COVID-19 Vaccines (Moderna update)* was presented by Shainoor Ismail (see presentation for details). NACI members were asked to review, resolve outstanding issues and approve new or updated NACI recommendations for mRNA vaccines. **Recommendation 1 (slide 6)** • No change to recommendation, presented edits - **APPROVED** **Recommendation 2 (slide 7)** • After fulsome discussion the majority of members and chair were in agreement with keeping the mention of preliminary evidence on asymptomatic infection under the rationale for Recommendation 2. • Proposed wording: *There is preliminary descriptive evidence suggesting Moderna COVID-19 vaccine may reduce asymptomatic infection but the implications are unclear and evidence is insufficient at this time to change the recommendation.* **Recommendation 3 (Slide 8)** • No change to recommendation, presented edits - **APPROVED** **Recommendations for populations excluded from clinical trials (Slide 9)** • No change to recommendation, presented edits - **APPROVED** **Recommendation 4: Immunocompromised Individuals (Slide 10)**	• [redacted] to poll colleagues and work with the NACI secretariat to identify potential appropriate lists of autoimmune conditions.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		• Additional presented edits - **APPROVED** **Additional Rationale for Immunosuppressed (Slide 12)** • Members supported the removal of bullet 2 completely, and the removal of the red proposed addition in bullet 3 • **APPROVED** with above changes **Recommendation 5: Individuals with Autoimmune Conditions (Slide 11)** • Several solutions were discussed, and it was decided that the establishment of a specific list of autoimmune conditions, or outlining of general underlying principles for decision-making in this population would be helpful. • Vice-chair suggested existing lists from reputable organizations could be linked in the NACI statement or added to the Canadian Immunization Guide • A member with applicable expertise offered to discuss with colleagues, and consider the following list: https://www.aarda.org/diseaselist/ **Additional Rationale for Auto-Immune (Slide 13)** • Discussion surrounded the importance of transparency regarding the rationale for this recommendation. It is geared towards jurisdictions and health care providers and they need something to communicate to patients. • The importance of bullet 1 to provide context for bullet 2 was discussed. There was a suggestion to reword bullet 1 as current wording could be worrisome.		

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status

		• Members supported the following changes:
		  ○ Reword bullet 2: to: "mRNA vaccines may elicit inflammation via activation of immune pathways".
		  ○ Reword bullet 3 to be positive: "Individuals with autoimmune disorders may benefit from the vaccine etc"
		
		• NACI secretariat suggested: "While it would prudent not *to routinely vaccinate all individuals with autoimmune disorders until more evidence is available, the balance of benefits and risks must be made on a case-by-case basis.* "
		
		• Chair will further consider if the above is appropriate in light of the potential safety signal.
		
		Recommendations 6 & 7 (Slide 14)
		• No change to recommendation, presented edits - **APPROVED**
		
		Additional rationale for pregnancy (Slide 15)
		• Presented edits – **APPROVED**
		• No opposition from members with regards to adding an "/or" to the following statement: "*Individuals who are pregnant, breastfeeding, or of reproductive age may be at increased risk of exposure to SARS-CoV-2 (e.g., healthcare or essential workers)* ***and/or*** *increased risk of severe COVID-19 disease…*"
		
		Recommendations 8 and 8a (Slide 16)
		• No change to recommendation, presented edits - **APPROVED**
		
		Post-Vaccination Counselling (Slide 18)		

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		• No change to recommendation, presented edits - **APPROVED** **Intervals Between Doses of COVID-19 Vaccine (Slide 19)** • No change to recommendation, presented edits - **APPROVED** **Maximum interval (Slide 20)** • No change to recommendation, presented edits - **APPROVED** **Interchangeability (Slide 22)** • The majority of members were in agreement with amended wording. Discussion included that with the antibody response, the vaccines are fairly comparable. • Concern was this could be interpreted by P/Ts as to give any mRNA vaccine available. • It was suggested to amend wording to "NACI strongly recommends that the vaccine series be completed with the same COVID-19 vaccine product. IF…." **Simultaneous admin with other vaccines (Slide 23)** • No change to recommendation, presented edits - **APPROVED** **Simultaneous admin with other vaccines (Slide 24)** • Presented additions to recommendation - APPROVED • Members discussed the rational surrounding the "28-day" interval. • NACI Chair suggests to leave this point for future discussion.		

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National Advisory Committee on Immunization
FINAL Record of Decisions
December 14 & 17, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
7.	**EEFA – Ethics Scenario based Analysis for Delayed Second Dose** For Discussion (Shainoor Ismail, NACI Secretariat)	• Members agree that this EEFA analysis is excellent and should be included in an appendix with the next iteration of the statement. • Members requested NACI Secretariat to arrange for presentation of this analysis at SAC **Next steps** • NACI members will receive Moderna statement once completed and approved by NACI Executive	• NACI Secretariat to work on EEFA analysis for inclusion into an appendix for next iteration of the statement. • NACI Secretariat to investigate soonest possible opportunity to present to SAC. • NACI Meeting January 4, 2020 – Cancelled. Re-scheduled to January 19, 2020	

ATIA - 19(1)

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National Advisory Committee on Immunization
DRAFT Record of Decisions
December 4 & 7, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
December 4, 2020				
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** For Information / Approval ([redacted] NACI Chair)	The NACI Vice-Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics, one member declared a potential COI to be discussed off line.	**Actions / Decisions** • Agenda for December 4 & 7, 2020 was approved.	
2.	**Update on status of COVID-19 vaccine submissions and authorizations** For Discussion / Approval (Matthew Tunis, NACI Executive Secretary)	Matthew Tunis shared anticipated timing of regulatory decisions for several COVID-19 vaccines while highlighting their impact on NACI's work moving forward. NACI shared commitment to deliver written COVID-19 vaccine guidance to PHAC shortly after regulatory approval. PHAC will support NACI with quick review and approval of its guidance.	• NACI Executive to discuss potential meeting for Monday, December 14, 2020	
3.	**Presentation of clinical evidence for Pfizer / BioNTech COVID-19 vaccine** For Discussion (Kelsey Young, Rob	NACI COVID-19 Vaccine Statement: Clinical Evidence was presented by the NACI Secretariat including: current phase 1/2/3 trial characteristics, vaccine efficacy, immunogenicity and safety evidence. The question and answer session covered the following topics: • Prophylactic and post immunization use of antipyretics • Serious Adverse Events Following Immunization	• Draft NACI statement will be circulated to all NACI + liaison members later on Friday, December 4, 2020. Members to please comment and use track changes.	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
	Sterling, April Killikelly & Oliver Baclic, NACI Secretariat)	• Study settings • Age range, pregnancy status and risk factors of participants • Antibody or immunogenicity markers following one dose vs. two doses • Different immunogenicity markers used in the studies • Study protocols surrounding risk factors, adverse event attribution and methods of reporting cumulative cases of COVID-19 in the analysis Finally, next steps were discussed including circulation of draft documents for comment and meeting materials to be reviewed to inform Monday's discussions.	• NACI and HCID WG members to review meeting materials in order to finalize recommendations on Monday, December 14, 2020	
December 7, 2020				
4.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** • RODs from November 25, 2020 For Information / Approval ([redacted] NACI Chair)	The NACI Chair opened the meeting and welcomed everyone. Members were invited to declare any new interests related to proposed meeting topics, none were declared. Members were informed that the new interest declared on Friday December 4, was not pertinent. The November 25, 2020 RODs have not yet been shared with NACI. Upcoming COVID-19 vaccine education webinars discussed and dates were provided. Chair indicated that NACI members may be approached to deliver COVID-19 vaccine webinars on behalf of PHAC.	• RODs from November 25, 2020 to be sent to the committee for approval at next NACI meeting.	

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National Advisory Committee on Immunization
DRAFT Record of Decisions
December 4 & 7, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
5.	**COVID-19 Vaccine Recommendations** For Approval (Shainoor Ismail, Kelsey Young, NACI Secretariat)	NACI Chair indicated that the initial COVID-19 Vaccine Recommendations will be discussed by the committee and final versions approved December 7 or 8, 2020) by the Chair and Vice Chair. NACI Recommendations will be then be submitted to PHAC for approval on December 8, 2020. *NACI Base Evergreen Statement: Recommendations on the use of COVID-19 Vaccines* presented by Shainoor Ismail. See presentation for details. Recurrent themes in this discussion included: • the paucity of evidence for decisions • the need for clarity in order to operationalize advice • inclusion or exclusion criteria from clinical trials • consideration of EEFA parameters • recommendations may be adjusted as more evidence becomes available • transparency about what is known and what is unknown at the current time The following recommendations were discussed: **Recommendation 1** NACI recommends that a complete vaccine series of COVID-19 vaccine should be offered to individuals 16 years of age and older without contraindications to the vaccine. In the context of limited vaccine supply, initial doses of COVID-19 vaccine(s) should be prioritized for the key populations outlined in NACI's Guidance on the Prioritization of Initial Doses of COVID-19 Vaccine(s). Presented changes were discussed and accepted. Recommendation 1 was approved as noted above.		

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		Recommendation 2 NACI recommends that COVID-19 vaccine may be offered to individuals 16 years of age and older with previously confirmed SARS-CoV-2 infection. In the context of limited vaccine supply initial doses may be prioritized for those who have not had a previously PCR confirmed SARS-CoV -2 infection. Recommendation 2 was accepted with the addition in the rationale sub bullets that: • there is no need to test prior to vaccination • strengthened information about lack of evidence **Recommendation 3** NACI recommends that all individuals should continue to take recommended public health measures to prevent infection with and transmission of SARS-CoV-2 regardless of vaccination with COVID-19 vaccine, at this time. Recommendation 3 was accepted with the following considerations: • NACI secretariat to inquire internally to confirm that updated public health measures will be put out in a timely fashion as evidence on vaccination's effect on transmission evolves. • In sub bullets need to be clear on the current lack of data regarding transmission at this time; noting that this will change as more evidence becomes available.	**Recommendation 2** Amend sub bullets as follows: • there is no need to test prior to vaccination • strengthened information about lack of evidence **Recommendation 3** NACI secretariat to inquire internally to confirm that updated public health measures will be put out in a timely fashion as evidence on vaccination's effect on transmission evolves Amend sub bullets as follows: • be clear on the current lack of data regarding transmission at this time; noting that this will change	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		Recommendations for populations excluded from clinical trials **Immunocompromised Individuals ≥16 yrs** NACI recommends COVID-19 vaccine should not be offered to populations who are immunosuppressed due to disease or treatment until further evidence is available (Strong NACI recommendation), however it may be considered if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population (Discretionary NACI Recommendation). • Above recommendation agreed to by all NACI voting members in principle, pending final edits by NACI Executive • There was significant discussion about the potential impact of mRNA vaccines on autoimmune disease, and the unknown potential for exacerbation due to immunological response to mRNA vaccine. Members agreed to take a conservative approach in the first guidance, and re-evaluate when discussing future vaccines. • Group consensus to use the same wording above for every group for which there is no data (e.g. pregnancy, breastfeeding; children & adolescents [discretionary for those under 16 years]). **Pregnancy** NACI recommends COVID-19 vaccine should not be offered until after completion of pregnancy and evidence is available	as more evidence becomes available **Recommendations for populations excluded from clinical trials** • Use the same wording for every group for which we have insufficient data (e.g. pregnancy, breastfeeding; children & adolescents [discretionary for those under 16 years]).	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		(Strong NACI recommendation). However it may be considered if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population *(Discretionary NACI Recommendation)* Above recommendation agreed to by all NACI voting members in principle, pending final edits by NACI Executive **Breastfeeding** NACI recommends COVID-19 vaccine should not be offered until after completion of breastfeeding and evidence is available (Strong NACI recommendation). However it may be considered if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population *(Discretionary NACI Recommendation)* **Children and Adolescents** NACI recommends that COVID-19 vaccine should not be offered to individuals <16 years of age. (Strong NACI Recommendation). However it may be considered in individuals 12 to 15 years of age if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccines in this population *(Discretionary NACI Recommendation)* **Administration Recommendations**	**Administration Recommendations** **Intervals between COVID-19 vaccine** • use "alternate" interval	

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National Advisory Committee on Immunization
DRAFT Record of Decisions
December 4 & 7, 2020

#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		Intervals between COVID-19 vaccine Approved with the use of "alternate" interval **Maximum Interval** Approved as presented on slide 21. **Interchangeability** NACI recommends that attempts should be made to complete the vaccine series with the same COVID-19 vaccine product (Strong recommendation). If the vaccine used for previously received doses is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g., mRNA vaccine) (Discretionary recommendation). No consensus achieved, interchangeability will be addressed in the next update to this guidance. **Simultaneous administration with other vaccines** Approved as presented on slide 23. **Post-vaccination counselling / Exclusion from work** Approved to remove from NACI guidance as outside NACI prevue. **Outbreak Settings** Approved to remove from NACI guidance as outside NACI prevue.	**Interchangeability** • To be brought forward in the next update when there will be two vaccines available **Post-vaccination counselling / Exclusion from work** • Remove **Outbreak Settings** • Remove	

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#	Agenda Item/Presenter	Discussion	Actions/Decisions	Status
		Vaccine, monoclonal Abs, convalescent sera Approved as presented on slide 26 without specification of an interval. *GRADE Evidence to Decision Framework* to be presented by Kelsey Young. See presentation for details. • Not discussed in detail due to the discussion that has already taken place at today's meeting. **Final Comments:** Secretariat and members thanked for extraordinary work. Member indicated it is important that the entire list of adverse events are referenced and flagged. Liaison member indicated may need to clarify suggested intervals between vaccines both before (14 days for non-live) and after (28 days) a COVID-19 vaccine.	NACI Secretariat: • Ensure list of all adverse events of special interest is flagged in statement • Specify the before and after interval between receipt of COVI-19 vaccine and other vaccines.	

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NACI High Consequence Infection Disease (HCID) Working Group:

COVID-19 Focus

RECORD OF DECISIONS

January 22, 2020 | 12:30pm – 2:00pm ET

Participants	**Working Group Chair:**	[redacted] (NACI Chair)
	Working Group Members:	[redacted] (NACI Vice-Chair), [redacted] Robert Pless, [redacted] Guillaume Poliquin, Matthew Miller
	NACI Secretariat	Matthew Tunis, Kelsey Young, Shainoor Ismail, Nicole Forbes, Austin Nam, Angela Sinilaite, Man Wah Yeung, Linlu Zhao, Oliver Baclic, Bryna Warshawsky, Ramya Krishnan, Yung-En Chung, Veronica Ferrante
	Invited speaker	
Regrets:		

Agenda Item #1

The committee chair welcomed working group members, NACI participants, and NACI Secretariat. The meeting agenda was approved as presented and no new conflicts of interest were declared for this meeting.

Action items: None

Agenda Item #2 Tuberculin Skin Test and Interferon Gamma Release Assay Testing Post-immunization with mRNA COVID-19 Vaccines

Presented by: Ramya Krishnan

NACI Secretariat presented on tuberculin skin tests (TST) at or around the time of COVID-19 mRNA vaccine administration and presented the group with proposed text for a NACI recommendation. The analysis was triggered by questions from HCP and updated guidance from CDC on the topic.

The presentation is available on CNPHI.

DISCUSSION/COMMENTS

- There were no objections with the proposed recommendation

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- One question was posed as to whether the same recommendation would be used for a viral COVID-19 vaccine, however there is currently no data surrounding testing for these vaccines.
- There was a brief discussion surrounding the 2-step TST and whether re-testing would be necessary in some instances. There is no data to address this question.

Action items: None

Agenda Item #3 – COVID-19 Vaccines Potential Allergens

Presented by: Joseline Zafack

NACI Secretariat presented on the updates to NACI recommendations proposed by the Vaccine Safety Working Group (VSWG) regarding allergic reactions following COVID-19 vaccination.

The presentation is available on CNPHI.

DISCUSSION/COMMENTS

- There was some concern that without a clear description of "mild to moderate" versus "severe" allergic reactions, it will be difficult to operationalize this recommendation. It was agreed that the recommendation should be re-worded to indicate that severe reactions refers to anaphylaxis and everything else should be considered non-severe.
- The group also discussed the reference to physician or nurse practitioner and agreed that the recommendation should be broadened to include "healthcare professional" in the context of those performing the risk assessment required for these individuals.

Action items: The VSWG Chair and Technical Leads will review the recommendation based on the discussion and will bring forward a revised recommendation to NACI.

Agenda Item #4 – Discussion Points for AstraZeneca COVID-19 Vaccine Candidate

Presented by: Matthew Tunis

NACI Secretariat presented high level evidence on the Astra Zeneca COVID-19 vaccine in anticipation of its authorization for use in Canada. It was intended to validate what should come forward at the upcoming NACI meeting in January 28th, 2021, to help the committee with their final deliberations.

The presentation is available on CNPHI.

DISCUSSION/COMMENTS

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- [redacted] Of those that indicated a preference, there was general agreement on recommending against the use in adults over the age of 65, and preferential use of mRNA for the rest, dependent on Health Canada authorization.
- There was a question about what to do with higher risk groups in lower age ranges. It was suggested that if there are contraindications to mRNA vaccines (i.e., allergy) or accessibility issues, that should be brought forward for further discussion. Consideration should also be made as to whether it is worth taking the risk for someone that had a reaction to an mRNA vaccine in a group for which efficacy of the AZ is largely unknown.
- There was concern about the potential impact of receiving the AZ vaccine now vs. a more efficacious mRNA vaccine later on long-term and overall effectiveness. Use of mixed schedule (AZ followed with mRNA) was discussed: administering the AZ vaccine and following up with an mRNA vaccine later, depending on availability. It was suggested that the PHAC Public Health Ethics Consultative Group should be consulted for input.

Action items: NACI secretariat will consult the Public Health Ethics Consultative Group next week and attempt to get input before the NACI meeting scheduled for January 28, 2021.

Agenda Item #5 – Discussion on Breakthrough Cases

Presented by: Matthew Tunis

The HCID WG Chair suggested that intervals may need to be considered.

DISCUSSION/COMMENTS

N/A

Action items:

N/A

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, April 13, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
1.	**Welcome and Introductions** • **Agenda**: Review and Approval • **Declaration of Interests** *For Information / Approval* (Presenter: [redacted])	The NACI Chair opened the meeting and welcomed everyone. An additional NACI meeting was scheduled for Thursday, April 15, 2021 from 3:00 – 4:30 PM EST to continue additional deliberations. Agenda was reviewed and approved. Members were invited to declare any new interests related to proposed meeting topics, no conflicts of interest were declared.	• Agenda for April 13, 2021 reviewed and approved.
2.	**Presentation: Health Canada assessment of AZ Terms and Conditions** *For Information* (Presenter: Kelly Robinson)	The presenter from the MHPD-HC provided an update on Health Canada's (HC) progress on the safety assessment of the AstraZeneca (AZ) vaccine. Items covered by this presentation included: • Timeline of major events that have occurred since the initial authorization of the AZ vaccine from international regulators (EMA and MHRA), HC, NACI, and the CMOH. • Actions taken by the EMA and MHRA and their conclusions. Overall, they have concluded that the benefits continue to outweigh the risks. • Data from AZ as of March 24, 2021 reporting on the incidence of thrombosis with thrombocytopenia by age and sex. The presenter highlighted there is a lack of identified specific risk factors which impacts the risk assessment/estimates of the rate of events in that there are no denominators for exposure by age/sex. • HC's assessment of the available data from the EMA, MHRA, and AZ. Following a review of the data, [redacted] • HC's ongoing communication with Janssen and their submission of their COVID-19 vaccine. • An update on AZ's provision of their benefit-risk assessment data by age/sex in response to the terms and conditions imposed by HC. Following the presentation, clarification was provided on the following points:	N/A

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ATIA - 21(1)(b) ATIA - 20(1)(c)

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#	Agenda Item/Presenter	Discussion	Actions/Decisions
		[redacted] • Although there are no identified specific risk factors for the AZ vaccine, HC's recommendation to weigh benefits vs risk in individuals with CVST and HIT is based on expert opinions from Thrombosis Canada and MHRA's communications around groups at high risk for blood clots. [redacted] • Rationale for recommending against individuals receiving the second dose of AZ vaccine if they have had a previous adverse reaction to the first dose. • HC is expecting to announce their assessment of the AZ vaccine and the label changes on April 14, 2021.	
3.	**Presentation: Update on AstraZeneca** *For Information* (Presenters: Joseline Zafack, Bryna Warshawsky, Shainoor Ismail)	The presenters from the NACI Secretariat presented an update on the vaccine induced immune thrombotic thrombocytopenia (VITT) situation in Canada, the epidemiology of COVID-19 in Canada, COVID-19 vaccine supply in Canada, and EEFA considerations and associated implications on NACI COVID-19 vaccine recommendations. Items covered by this presentation included: [redacted] • Epidemiology of COVID-19 in Canada including incidence of COVID-19 by age group, incidence of hospitalization due to COVID-19, incidence of ICU admissions due to COVID-19, weekly mortality rate due to COVID-19, the incidence of variants of concern (VOC), and hospitalization associated with VOC. • Anticipated COVID-19 vaccine supply for each type of COVID-19 vaccine for 2021 Q2 and Q3.	N/A

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National Advisory Committee on Immunization

Record of Decisions

Tuesday, April 13, 2021

#	Agenda Item/Presenter	Discussion	Actions/Decisions
		• EEFA considerations related to COVID-19 vaccination in Canada and proposed changes to current NACI COVID-19 vaccine recommendations.	
4.	**Discussion: Discussion on AZ and Janssen** *For Discussion/Decision* All	Following the presentation, there was a discussion regarding whether the age restriction associated with the AstraZeneca vaccine should be removed. [redacted] **Treatment of AZ and JJ vaccines** • The committee voted and there was full membership consensus that the AstraZeneca and Janssen vaccines should be treated similarly in the NACI COVID-19 vaccine recommendations.	• PHAC to prepare a risk benefit analysis by age group including the wait time to get an mRNA vaccine.
5.	**Next Steps** *For Information* (Presenter: [redacted])	The committee will continue their deliberations on Thursday, April 15, 2021 from 3:00 PM – 4:00 PM EST.	

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PHAC-A-2021-000080

Request Text :

"Requesting final version of reports, briefing notes, and meeting records from formal working groups/committees in possession of the Government of Canada pertaining to the discussion of the risk of injury or death caused from vaccinations for COVID-19 administered in Canada. As well, requesting all final documentation on the obligations of Canadian governments for victim compensation regarding injuries or deaths from COVID-19 vaccines, including the creation of the vaccine injury compensation program. I am NOT requesting personal medical information or communication records of individuals emailing PHAC about the compensation program. All documentation can be limited to the Director General level and above. All documentation can be limited to the period of November 2019 to present."

Response:

Re Final version of reports: Please consult the online report entitled **Reported side effects following COVID-19 vaccination in Canada (**https://health-infobase.canada.ca/covid-19/vaccine-safety/) for the most recent report. These reports are updated every Friday afternoon unless otherwise stated on the web page. Archived reports from the start of this online report on January 8 2021 are available on the web page entitled **Archived vaccine safety reports (**https://health-infobase.canada.ca/covid-19/vaccine-safety/archive/)

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, July 16, 2020 from 12:30 – 2:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB** [redacted] **NS:** [redacted] **NU** [redacted] **ON (Ministry):** [redacted] **ON (PHO):** [redacted] **PE:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
CSC: Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **RCMP:** Natalie Toupin, **IMPACT** [redacted] **BRDD:** Robert Pless, **FNIHB:** Joan Reiter, **MHPD:** Jhona Rose; Battouli Said Salim; Deborah Danoff

Observers/Presenters in Attendance:
Nooshin Ahmadipour, Helen Anyoti, Andrew Atabe, Nicolas Gilbert (Federal Co-Chair), Saundra Houle, Karin Johnson, April Killikelly, Jean Nkanza

Regrets:
NB: [redacted] **NL:** [redacted] **NT:** [redacted] **QC** [redacted]

ACTION ITEMS

1. **Follow up action item (from June 18 2020 RoD):**
   PHAC to continue working on a plan for expedited reporting of AEFIs from COVID-19 vaccination and active surveillance.
2. **Solar Surveillance System Demo:**
   Karin to follow up with P/Ts individually regarding feedback on the proposed expedited influenza template.
   VVWG members to email Karin with any questions regarding the Solar Surveillance System Demo.
3. **Active Surveillance Task Group - Update**
   The Active Surveillance Task Group to hold their next meeting in September and have a more refined proposal ready to present at October VVWG call.
4. **COVID-19 Vaccine Developments**
   Members to send any questions for April to VVWG secretariat.
5. **COVID-19 Vaccine Regulatory Process**
   Members to send any questions for Robert to VVWG secretariat.

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Robert to make additional revisions to his part of the presentation and send to VVWG members.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of June 18 2020 RoD	a) Agenda was approved: No new items were added. b) RoD was approved: No changes were made. Follow up action item: ***i. Expedited Reporting of AEFIs from COVID-19 Vaccination*** ***- PHAC to present plan for monitoring the safety of future COVID-19 vaccines to senior management and CIC.*** Nicolas mentioned he briefed his DG and presented an update at CIC. However, further work is required on both the expedited reporting and active surveillance before presenting a plan to senior management and CIC.	Nicolas	**ACTION:** a) No action. b) No action. i. PHAC to continue working on a plan for expedited reporting of AEFIs from COVID-19 vaccination and active surveillance.
2. Solar Surveillance System Demo	a) Karin indicated an email was sent out to the VVWG members about the proposed expedited influenza template and some P/T feedback was received. She also mentioned automated data entry for expedited influenza reporting is being considered.	Karin / Andrea Nwosu	**ACTION:** a) Karin to follow up with P/Ts individually regarding feedback on the proposed expedited influenza template.

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Agenda Item	Description	Lead	Further Actions or Completed
	b) Andrea provided a live demonstration of the Solar Surveillance System. It is accessed via the secure website, CNPHI, and is used for outbreak and level of activity reporting. She outlined the following: - Dashboard: Serves as main area for summary of data. All data is visualized, projected and updated in real time. She noted that P/Ts can only access their own data and the overall national picture. - Status and notifications: Notifies each P/T of status updates. - Uploaders: Provides outbreak, activity, and PTSOS details. - P/T reports: Activity levels including previous reports with new data and report history. Andrea proceeded to provide a sample upload of activity level data displaying the following: - Indicated how many records uploaded and how many did not. - Provided an upload status and indicated where errors occurred (i.e., validation checks are performed to indicate record errors and where the issues lie).		b) VVWG members to email Karin with any questions regarding the Solar Surveillance System Demo.
3. Active Surveillance Task Group - Update	a) Nicolas stated the Active Surveillance Task Group had their first meeting July 2, 2020. During this call, options were identified and the group will continue working to develop and explore various possibilities.	Nicolas	**ACTION:** a) The Active Surveillance Task Group to hold their next meeting in September and have a more refined proposal ready to present at October VVWG call.

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Agenda Item	Description	Lead	Further Actions or Completed
4. COVID-19 Vaccine Developments	a) April presented on the Canadian Vaccine Development Landscape. Topics included: - Preclinical development - Vaccine development - Clinical development (current snapshot): Medicago and CanSino have obtained regulatory authorization to initiate clinical trials in Canada.	April Killikelly	**ACTION:** a) Members to send any questions for April to VVWG secretariat.
5. COVID-19 Vaccine Regulatory Process	a) Robert presented on Canadian Vaccine Regulatory Authorization. Topics included: - Food and Drugs Act and Regulations: orientation - Guidelines (e.g., regulations, flexibilities, international guidelines) - Vaccine product life cycle - Life cycle 1: Clinical trial review - Life cycle 2: Submission for market authorization - Vaccine NDS review process - Notes on review - Regulatory submission pathways - Examples of regulatory flexibility (e.g., Usual process versus interim order) - Clinical trials interim order (e.g., Usual process versus interim order)	Robert Pless	**ACTION:** b) Members to send any questions for Robert to VVWG secretariat. Robert to make additional revisions to his part of the presentation and send to VVWG members.
6. Roundtable		All	**ACTION:**

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Agenda Item	Description	Lead	Further Actions or Completed
	a) No items discussed.		a) No action.
7. Confirm Next Call	a) Next regular call: September 17, 2020	Nicolas	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, June 18, 2020 from 12:30 – 2:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB** [redacted] **NL** [redacted] **NT** [redacted] **NS:** [redacted]
[redacted] **NU:** [redacted] **ON (PHO):** [redacted] **PE:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **RCMP:** Natalie Toupin, **IMPACT:** [redacted] **BRDD:** Robert Pless, **FNIHB:** Joan Reiter, **MHPD:** Jhona Rose; Battouli Said Salim; Deborah Danoff

Observers/Presenters in Attendance:
Nooshin Ahmadipour, Helen Anyoti, Andrew Atabe, [redacted] Nicolas Gilbert (Federal Co-Chair), Saundra Houle, Karin Johnson, [redacted]

Regrets:
NB: [redacted] **ON (Ministry):** [redacted] **QC:** [redacted] **CSC:** Samar Sarkesh

ACTION ITEMS

1. **Expedited Reporting of AEFIs from COVID-19 Vaccination**
   - PHAC to present plan for monitoring the safety of future COVID-19 vaccines to senior management and CIC.

2. **Active Surveillance of AEFIs: The Quebec Experience with Bexsero in 2014**
   - PHAC to send relevant articles on Bexsero to VVWG members.

3. **Active Surveillance of AEFIs from COVID-19 Vaccination**
   - PHAC to send out a follow up email to VVWG members seeking volunteers for the Active Surveillance Task Group.

4. **Expedited Influenza Reporting Template**
   - PHAC to send the expedited influenza reporting template to VVWG members for approval.
   - Expedited reporting for COVID-19 to be discussed further on the July 16 call.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of May 21 2020 RoD	a) Agenda was approved: No new items were added. b) RoD was approved: No changes were made.	[redacted]	**ACTION:** a) No action. b) No action.
2. Expedited Reporting of AEFIs from COVID-19 Vaccination	a) Karin delivered a presentation on expedited reporting of AEFIs following COVID-19 vaccination highlighting these details: - Background information: Candidate COVID-19 vaccines in development, anticipation of mass vaccination campaign, and PHAC's plan to monitor safety of future COVID-19 vaccines. - Decision sought: Requested VVWG's approval of the principle of expedited reporting of AEFIs during COVID-19 mass vaccination. Result: VVWG members supported this decision.	Karin	**ACTION:** a) PHAC to present plan for monitoring the safety of future COVID-19 vaccines to senior management and CIC.
3. Active Surveillance of AEFIs: **- The Quebec Experience with Bexsero in 2014** **- CANVAS: Influenza Vaccine**	a) [redacted] presented a summary on safety monitoring of the mass Bexsero immunization campaign in the Saguenay-Lac-Saint-Jean region, Quebec. Topics discussed were as follows: safety	[redacted]	**ACTION:** a) PHAC to send relevant articles on Bexsero to VVWG members.

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Agenda Item	Description	Lead	Further Actions or Completed
	of Bexsero (e.g., signals from clinical trials), enhanced safety surveillance (e.g., passive), safety assessment (e.g., active surveillance), AEFI Validation, control series. Jhona (MHPD) – Requested more detail on the potential AEFI signal of nephrotic syndrome from Bexsero vaccination. [redacted] offered to provide article links with further information. b) [redacted] provided an overview of Canadian National Vaccine Safety (CANVAS) Network's active safety surveillance for influenza vaccine. Highlights included the following: objective of CANVAS, vaccine safety surveillance, COVID-19 proposed surveillance, severe event definition, specific event definitions.		b) No action.
4. Active Surveillance of AEFIs from COVID-19 Vaccination	a) Nicolas provided a presentation on active surveillance of COVID-19 vaccine(s) in target populations. The following items were outlined: objective (e.g., enhanced surveillance in CAEFISS), approach (e.g., target groups), method, data processing, possible data analysis, reporting to VVWG, and next steps. Nicolas indicated the next step would be to form a task group (including health jurisdictions and experts) to explore active surveillance of AEFIs from COVID-19 vaccination (e.g., develop a more detailed proposal and plan). VVWG members supported the creation of this task group and	Nicolas	**ACTION:** a) PHAC to send out a follow up email to VVWG members seeking volunteers for the Active Surveillance Task Group.

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Agenda Item	Description	Lead	Further Actions or Completed
	interested members included those from AB, BC, IMPACT, and CANVAS.		
5. Expedited Influenza Reporting Template	a) Karin asked VVWG members if the template used for expedited influenza reporting last season remains acceptable for the upcoming season. b) With respect to expedited reporting for COVID-19, Karin mentioned PHAC is currently exploring the option to automate this data reporting via CNPHI.	Karin	**ACTION:** a) PHAC to send the expedited influenza reporting template to VVWG members for approval. b) Expedited reporting for COVID-19 to be discussed further on the July 16 call.
6. Roundtable	a) [redacted] (BC) mentioned Fluad will be added to their list for this year's influenza season.	All	**ACTION:** a) No action.
7. Confirm Next Call	a) Next regular call: July 16, 2020	Nicolas	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 21, 2020 from 12:30 – 2:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC** [redacted] **MB** [redacted] **NT** [redacted] **NU:** [redacted] **ON (PHO):** [redacted] **PE:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
IMPACT: [redacted] **BRDD:** Robert Pless, **FNIHB:** Andrea Gartley, **MHPD:** Jhona Rose

Observers/Presenters in Attendance:
Nooshin Ahmadipour, Helen Anyoti, Andrew Atabe, Nicolas Gilbert (Federal Co-Chair), Saundra Houle, Christina Jensen, Karin Johnson, Jennifer Pennock, [redacted]

Regrets:
NB: [redacted] **NL:** [redacted] **NS:** [redacted] **ON (Ministry):** [redacted] **QC:** [redacted] **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **RCMP:** Natalie Toupin

ACTION ITEMS

1. **Proposed enhanced surveillance activities**
   Nicolas: Confirm presentation for June 18 call with QC VVWG member (i.e., 2014 active surveillance of AEFIs following Bexsero mass vaccination).
2. **Interactive dashboard for reporting products**
   VVWG members: Agreed with use of the proposed interactive dashboard as PHAC's new reporting scheme and having it posted publicly online.
3. **Signal Response Protocol SOP**
   VVWG members: Review the Signal Response Protocol SOP presentation and email PHAC with any questions or comments regarding its revisions.
4. **Roundtable**
   Robert (BRDD): Email VVWG members with draft paragraph for a new statement on recording product information for all vaccine product monographs.
   Jhona (MHPD): Send follow up email to VVWG members requesting input on the revised AEFI reporting instructions found on the Canada Vigilance website.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of January 23 2020 RoD	a) Agenda was approved: No new items were added. b) RoD was approved: No changes were made. Action item: Signal Response Protocol – threshold table - Karin was seeking VVWG approval on the proposed methodology and denominator data. - VVWG was in agreement to proceed with methodology and the use of Option 2 for the denominator data (i.e., calculate the 5-year average using doses distributed).	Nicolas	**ACTION:** a) No action. b) Karin will proceed with work on the Signal Response Protocol – threshold table.
2. Lessons learned from the pH1N1-09 pharmacovigilance	a) Nooshin provided a presentation on lessons learned from pH1N1-09 pharmacovigilance in Canada. Topics included: - Workings of the Vaccine Vigilance Task Group (VVTG) - Highlights of the VVTG Survey - Challenges at the PHAC - What worked well during the pandemic - What improvements were identified for future pandemic situations - Conclusions from the VVTG Survey	Nooshin	**ACTION:** a) No action.
3. Proposed enhanced surveillance activities		Nicolas	**ACTION:**

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Agenda Item	Description	Lead	Further Actions or Completed
	a) Nicolas provided a presentation on proposed enhanced surveillance activities for monitoring COVID-19 Vaccine Safety. Highlights included: - CAEFISS: Preparing for safety monitoring of COVID-19 vaccine (i.e., SOPs, timeliness and accessibility of PHAC reporting/updates) - Collaborations: Preparing for safety monitoring of COVID-19 vaccine (i.e., expansion of VVWG; coordination with HC; linkages with CANVAS and PT active surveillance; connection with international regulatory and public health partners; and data sharing with MAHs).		a) No action.
	b) Nicolas invited VVWG QC member to present on Quebec's experience with active surveillance of AEFIs following Bexsero mass vaccination in 2014 (e.g., development and implementation of surveillance system).		b) Nicolas: Confirm presentation for June 18 call with QC VVWG member (i.e., 2014 active surveillance of AEFIs following Bexsero mass vaccination).
	c) [redacted] (IMPACT) commented that although children may not be the first target for vaccine, IMPACT is willing to liaise with PHAC and PTs expand extended surveillance.		c) No action.
	d) Robert Pless (BRDD) mentioned from the BRDD perspective, improvements in transparency will allow sharing of regulatory processes and candidates.		d) No action.
4. Interactive dashboard for reporting products	a) Karin provided a presentation on an interactive dashboard for PHAC reporting products.	Karin/Allison	**ACTION:** a) VVWG members: Agreed with use of the proposed interactive

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Agenda Item	Description	Lead	Further Actions or Completed
	- VVWG feedback was being sought on reporting national level influenza vaccine AEFIs via a dashboard. - VVWG approval was being sought to make the dashboard available publicly. - Using seasonal influenza data from 2014/15 to 2018/19, Karin presented a dashboard overview (e.g., explanation of button options). [redacted] (ON - PHO) asked how this dashboard would affect AEFI counts for influenza seasons. Karin indicated the proposed dashboard would replace the current bi-annual/annual AEFI reporting formats. However, PHAC is working to simplify expedited influenza AEFI reporting.		dashboard as PHAC's new reporting scheme and having it posted publicly online.
5. Signal Response Protocol SOP	a) Nooshin presented an overview of the Signal Response Protocol SOP. Due to meeting time constraints, VVWG members were asked to review the deck at their leisure.	Nooshin	**ACTION:** a) VVWG members: Review the Signal Response Protocol SOP presentation and email PHAC with any questions or comments regarding its revisions.
6. Roundtable	a) Robert Pless (BRDD) requested feedback from VVWG members regarding a proposal to update all vaccine product monographs with a new statement on recording product information. b) Jhona Rose (MHPD) mentioned revisions to AEFI reporting instructions on the Canada Vigilance	All	**ACTION:** a) Robert: Email VVWG members with draft paragraph for a new statement on recording product information for all vaccine product monographs. b) Jhona: Send follow up email to VVWG members requesting

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Agenda Item	Description	Lead	Further Actions or Completed
	website were previously circulated to VVWG. She asked if there was any additional feedback.		input on the revised AEFI reporting instructions found on the Canada Vigilance website.
7. Confirm Next Call	a) Next regular call: June 18, 2020	Nicolas	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, November 12, 2020 from 12:30 – 1:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
BC: [redacted] **AB:** [redacted] **MB:** [redacted] **NB:** [redacted] **NL:** [redacted] **NT:** [redacted] **NS** [redacted] **NU:** [redacted] **ON (Ministry):** [redacted] **PE:** [redacted] **QC:** [redacted] **SK:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **BRDD:** Robert Pless, **FNIHB:** Melanie Knight, **MHPD:** Jhona Rose, Battouli Said Salim, Shiva Ghimrie **CSC:** Samar Sarkesh, **IMPACT:** [redacted]

Observers/Presenters in Attendance:
Nooshin Ahmadipour, Helen Anyoti, Andrew Atabe, Karin Johnson, April Killikelly, [redacted] Allison Yeung, Amanda Shaw (Federal Co-Chair), Tracy Freeland, Carmen Salinas, Eugenie Samson, [redacted]

Regrets:
RCMP: Natalie Toupin, **YT:** [redacted]

ACTION ITEMS

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda	a) Agenda was approved. No new items were added.	Karin	**ACTION:** a) No action.

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Agenda Item	Description	Lead	Further Actions or Completed
2. Objectives of the meeting • **To determine PTs interest in participating in active surveillance** • **To determine PT resources available and resources needed for active surveillance**	a) Presentation provided by Karin on Active Surveillance Program Monitoring adverse events following COVID-19 vaccine(s) b) Presentation provided by Julie Bettinger on CANVAS's potential role in active surveillance	Karin Johnson	**ACTION:** a) No action.
3. Overview of active surveillance and options for roll out	Outline of active surveillance options: Note: Not going to proceed with a PHAC led active surveillance. a) Looking at PTs leading their own active surveillance b) Using CANVAS led active surveillance Karin provided her presentation on Active Surveillance Program Monitoring adverse events following COVID-19 vaccine(s)	Karin Johnson	**ACTION:** a) No action.
4. Potential role of CANVAS's in active surveillance	[redacted] provided her presentation on Canadian National Vaccine Safety (CANVAS) Network: Active Safety Surveillance for Influenza Vaccine	[redacted]	**ACTION:** a) After the call, if there are PTs interested in doing active surveillance, PHAC will provide a costing template.

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Agenda Item	Description	Lead	Further Actions or Completed
	a) CANVAS planning for COVID-19 vaccines and need for PT support beyond existing sites/populations b) CANVAS existing recruitment: current network consists of 40,000 participants. In Vancouver, the recruitment consists of HCP, children and the general public. In Calgary, the current network consists of HCP, children, general public and the ability to recruit in LTC. A PH partner for recruitment is required outside of Calgary. There are two sites in Ontario: Ottawa (The Ottawa General Hospital) and Toronto (St. Michael's Hospital). In Ontario, there is a need for a PH partner for broader recruitment. c) Recruitment strategies: enhance safety surveillance or provide CANVAS with an electronic list with required registration info d) Follow up medically attended events: currently, the process is to follow up with a phone call. If expanded, CANVAS would want to discuss this process with each jurisdiction interested in active surveillance		b) PHAC will send out a template with resourcing requirements. c) Karin will contact the PHAC contract department to see what options are available for funding. She will look to see what is involved if AB is interested.

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Agenda Item	Description	Lead	Further Actions or Completed
	e) Decision points for PTs with CANVAS sites. Currently, there are no sites in NB and PEI f) Decision points for PTs without a CANVAS site. Would those jurisdictions be willing to partner with an existing site or create a new one? g) Additional consideration: i. Jurisdictions without good administrative data and vaccine registry data linkages, should consider capturing personal health number in case additional analyses are needed. For instance, ability to link with other data sources (i.e. lab-testing data; hospitalization data, vital stats data). **Questions/Answers** 1. Karin asked if there are PTs interested in partnering with CANVAS or taking on active surveillance by themselves? 2. [redacted] answered [redacted] (MB) question about participants: need a minimum of 25,000 participants per vaccine.		

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Agenda Item	Description	Lead	Further Actions or Completed
	3. [redacted] (BC) commented with respect to long-term care residents, there would not have a good control group in that population. [redacted] answered with the following: Think about the long term care residents as 2 groups: a) Frail physically but mentally well: this group could manage the technology to complete the CANVAS survey. b) Physically frail and mentally unable: CANVAS would use a proxy. It would be necessary to have a need for someone, who is available, to complete the survey for that individual. c) Control group: would be challenging in a long-term care population. The match would not be as good but it is possible.		

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Agenda Item	Description	Lead	Further Actions or Completed
	4. [redacted] (NB): Would NB be affiliated with the Halifax site? [redacted] answered: Yes. Would the results be shared at national level or breakdown at PT? [redacted] answered: CANVAS does both currently with flu and would do the same for COVID-19 vaccine. 5. [redacted] (MB): Would we still get national data from CANVAS even if they did not partner with them? [redacted] answered: Yes they can, will need to have discussion with PHAC regarding weekly calls and sharing of data like they currently do each flu season. 6. [redacted] (ON - Ministry): Do we know what post market surveillance will look like from the manufacturers? Amanda Shaw answered: No, we do not know how information will be shared with CAEFISS from manufacturers at this point. Perhaps Jhona (MHPD) could comment on Canada Vigilance? Jhona (MHPD) answered: There will be a risk management plan where activities will be identified from the companies for events of interest or potential risks and companies are to rapidly communicate any AEFIs. She also mentioned moving towards monthly or bi-monthly PSURS.		

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Agenda Item	Description	Lead	Further Actions or Completed
	7. Robert (BRDD): CanImmunize app: Any ideas to expand it beyond the few jurisdictions? [redacted] answered: Yes, they are testing it now. It will be one way to expand the reporting. Some prefer email with a link. It is definitely an option assuming it works well and gets used. 8. [redacted] (ON - Ministry): If Ontario were to expand beyond the current, two CANVAS sites would PHAC be able to support this? Karin answered: Yes, we will follow up from this call with a template requesting what you would need for funding. If there are PTs interested in doing active surveillance, PHAC will provide a costing template. [redacted] asked: Can sites be expanded beyond healthcare workers? [redacted] answered: Yes. 9. [redacted] Karin mentioned that she needs to meet with the contract division to see what options are available for funding. She will		

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Agenda Item	Description	Lead	Further Actions or Completed
	look to see what is involved if AB is interested. 10. Karin is interested in knowing which PTs are interested in partnering with CANVAS for active surveillance. PHAC will send out a template with resourcing requirements. Then CANVAS would have to have individual discussions with PTs to see about partnering with other sites, etc. Who is interested in partnering with CANVAS? [redacted] (BC) asked when does PHAC need a firm answer? Karin answered: Sooner rather than later. Karin will send out template tomorrow to see what resources / costing PTs require. She asked if that seemed reasonable? It is a quick turnaround and have a deadline set for next week.		
5. Round table – PT interest in participating, preferred option, resources and needs	a) BC and QC expressed an interest in partnering.	ALL	**ACTION:** a) No action
6. Next Steps	a) PTs will need to respond by next week if they are interested in partnering with CANVAS on active surveillance during the COVID-19 vaccination campaign	ALL	**ACTION:** Karin to send out to the VVWG via email:

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Agenda Item	Description	Lead	Further Actions or Completed
	b) PTs will need to determine the costing out of resources to support jurisdictions with active surveillance during the COVID0-19 vaccination campaign. c) Any questions regarding the CANVAS presentation can be emailed directly to [redacted] or the VVWG email account.		a) Template to assess jurisdictional interest in partnering with CANVAS on active surveillance during the COVID-19 vaccination campaign. b) Template for costing out resources to support jurisdictions with active surveillance during the COVID-19 vaccination campaign.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Monday, November 16, 2020 from 12:30 – 1:30 PM EST
Record of Decisions (RoD)
Special Meeting – Flu Laval Tetra Alert

Members in Attendance:
BC: [redacted] **AB:** [redacted] **MB:** [redacted] **NB:** [redacted] **NL:** [redacted] **NS:** [redacted] **ON (Ministry):** [redacted] **PE:** [redacted] **QC** [redacted] **SK:** [redacted]

Liaison Members in Attendance:
CSC: Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **BRDD:** Robert Pless, Nathalie Fortin, **FNIHB:** Melanie Knight, **MHPD:** Jhona Rose, Battouli Said Salim, Shiva Ghimrie, Deborah Danoff, **IMPACT:** [redacted]

Observers/Presenters in Attendance:
Nooshin Ahmadipour, Helen Anyoti, Andrew Atabe, Karin Johnson, Allison Yeung, Amanda Shaw (Federal Co-Chair), Tracy Freeland, Carmen Salinas, Eugenie Samson, [redacted] Jennifer Pennock, Leanne Coward, Michael Austin, Althea House, Angela Sinilaite, Rob Stirling, Saundra Houle, Andrea Gartley

Regrets:
NT: [redacted] **NU:** [redacted] **YT:** [redacted] **RCMP:** Natalie Toupin,

ACTION ITEMS

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, a) Review and approval of agenda	a) Agenda was approved. No new items were added.	Amanda Shaw / Jennifer Pennock	**ACTION:** a) No action.

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Agenda Item	Description	Lead	Further Actions or Completed
	b) Jennifer provided an opening statement. She thanked everyone for attending on such short notice. She also thanked NB for making us aware and for doing the CNPHI alert on Friday, November 13, 2020. Jennifer advised that the deployment of the COVID-19 vaccine would start in 2021. The safety of the vaccine will be something many people will be interested in. The confidence of the public in having a safe and effective vaccine is going to be fundamental for when they make their choice to get vaccinated. Jennifer noted that vaccine safety signal is something important and something we need to pay attention to. Today's discussion will help us think about how we will handle safety signals going forward particularly for the rest of the season of COVID-19.		
2. FluLaval Tetra Alert Summary	a) On Friday, November 13, 2020, PHAC received an alert from NB of three AEFIs (all neurological and in adults) related to FluLaval Tetra vaccine lot # KX9F7. New Brunswick Public Health advised providers in the province to suspend the use of the LOT number in question until further investigation. New Brunswick also published the alert on CNPHI on Friday, November 13, 2020 in the afternoon.	Amanda / Jennifer	**ACTION:** a) The presentation on **FluLaval Tetra Vaccine Alert Summary** will be circulated after the meeting b) PHAC would like to know which PTs have received Lot KX9F7 or J4429, how many doses were received

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	b) Health Canada was informed of the alert on Friday afternoon and informed the manufacturer (GSK). Health Canada Indicated that KX9F7 is a package lot and related to it is lot number J442P. Further analysis and follow up will be forthcoming. c) Five AEFIs have been reported for FluLaval Tetra vaccine related to lot # KX9F7 d) No AEFIs have been reported for FluLaval Tetra vaccine related to lot # J442P e) PHAC has requested that all PTs notify the Agency of any additional cases in their jurisdictions. Vaccine Safety has requested that PTs review their AEFI databases and notify us of any cases related to FluLaval Tetra Lot KX9F7 or J4429. f) As of Sunday, November 15, 2020, New Brunswick, Manitoba and Saskatchewan have all suspended the administration of Flulaval Tetra Lot number KX9F7 vaccines. g) The presentation displayed a GSK table showing the distribution of FluLaval Tetra vaccine lot # KX9F7 2020. This lot was distributed to six PTs (ON, QC, NS, MB, SK, NB) as of September 25, 2020 h) **PT Situation** - We received feedback from other provinces. The following is feedback from 6 provinces who received the lot in question: NB received the lot in question. The lot has been distributed but not sure if they have all been administered. NB has noted 3 AEFIs and 2 are serious in relation to this lot. NB has advised their		and how many have been administered?

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	health care providers to stop administering the lot in question. QC has received the lot in question and administered all doses. They have no serious AEFIs reported in relation to this lot. BC did not receive the lot but they have noted 8 AEFIs associated with FluLaval Tetra but not the lot in question but another lot with the distribution from this year. MB received this lot and has administered almost all of their lot in question. They have not seen any AEFIs but have suspended the administration. SK received this lot ands has administered all doses. They do not have any AEFIs but as a precaution, they have suspended the use of this lot. ON received this lot and they have reported no AEFIs for this lot. ON has also suspended the use of this lot.		
3. Update from CAEFISS analysis	Initial analysis done on our expedited reporting. a) As of week 45, there are a total of 186 AEFIs reported and 40% of those were following immunization with FluLaval Tetra. 53% were non-serious and 21% were serious adverse	Karin	**ACTION:** a) No action.

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	events. The total amount of doses distributed were 13 million and total amount of FluLaval Tetra doses distributed was 5 million which makes up 38% of the overall vaccines distributed this season. b) The table below on slide 6 in the presentation, outlines the adverse events that have been reported following immunization with FluLaval Tetra. The table is broken down by total number of AEFIs, number of serious and number of non-serious. For all the serious AEFIs, Karin has put the lot number that has been associated with it. In total we had 21 serious AEFIs, 11 of those are medically important events reported by MHPD. Regarding the lot number in question, their is 1 GBS, 1 Bell 's Palsy, 1 transverse myelitis. There is another report of anaphylaxis with the KX97 lot number. The anaphylaxis case that was reported with the long number. It is the incorrect lot number. PHAC is looking into this with MHPD to clarify this case. We have 4 serious adverse events and another 4 that are medically important adverse events. Comparing to other influenza seasons with the expedited reporting we have had no neurological events for the last few influenza seasons. The last time we had a neurological event reported was in 2016-17 (one GBS case). We looked into the CAEFISS data and we looked into the number of neurological events and for this year we found that we have 3 neurological events that include, 1		

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	Bell's Palsy and 2 GBS. At this time, we are still undergoing QA for a few other reports. In 2019 we had 8 neurological symptoms, cases that were reported as numbness and tingling. In 2018-19 we had 1 neurological event reported (seizure) and 13 neurological symptoms (numbness and tingling). In 2017-18 we had had 1 neurological event reported (seizure) and 17 neurological symptoms (numbness and tingling) reported. **QUESTIONS:** 1. **NB:** Do we have the total number of FluLaval Tetra doses from the KX9F7 lot? **Responded by Amanda:** The total number of doses distributed was 1.2 million at the end of September and another 200,000 in early October. [redacted] **(MHPD):** In ON for example, there are two lot numbers. They are not distinguishing which lot. Robert Pless: The 665,000 is a different lot and the more than 575,000 is the KX lot 2. **NB:** How do you distinguish between neurologic and medically important? You mentioned that there are several cases with numbness and tingling, which would be a difference in degree.		

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	Responded by Helen: Numbness and tingling can also be associated with vaccination sites reaction because some of the cases that we have now are numbness and tingling at vaccination sites and we have seen numbness and tingling in an individual who developed butcher carrier. Therefore, it is not specifically to the neurological event such as myelitis only. They did not code it as symptoms but as another event. Most likely localised. [redacted]**rom CANVASS - Comment:** We looked at the CANVASS data recently, over the past 6 years, specifically numbness and tingling and it is so non-specific that you cannot use it to pick out neurologic events.		
4. Update from Canada Vigilance	a) How are the medically recorded events recorded with Canada Vigilance? Our Canada Vigilance database is coming from the MAH and our recording criteria, based on the recent seriousness, are one of the categories called the "other medically important events." Battouili highlighted what they have retrieved so far 11 cases related to lot number KX9F7 and no cases from the other lot number. They did not find neurological events related to lot number KX9F7. They have one that was mentioned as not serious.	Jhona/Battouili/ Shiva	**ACTION:** a) Battouili from MHPD will follow up with Canada Vigilance on lot number 20621 to confirm the exact number. b) When NB posted the alert on CNPHI, it was posted under "General alert." What we are trying to do is to make sure that the alerts are posted directly within the AEFI section of CNPHI. This was moved and it did cause a bit of a

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	In regards to Lot number 20621, Battouili will follow up with Canada Vigilance to confirm the exact lot number. **Questions:** 1. [redacted] (BC): In these events, they may not be added to the CAEFISS reports, there could be duplicates across the system the two systems is this correct? **Responded by Battouili:** What is being reported to the Canada Vigilance is that they are coming from the manufacturer or the MAH (GSK in this case) and it is also being recorded by CAEFISS and also coming from PTs. 2. ON: One incident on October 23, 2020 with the [redacted] It was recorded to the Local Public Health but it does not look like it was been recorded yet. **Responded by Karin:** If the report was sent to the province, we may not have received the case report form yet. If it was not reported in expedited reporting, it may be a reporting delay. Helen Anyoti confirmed that yes, it is a reporting delay. 3. **MB** [redacted]: Previous years national influenza AEFI data.		delay in terms of other people seeing it. Just a reminder to everyone to post alerts under this section.

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	Responded by Karin: We are reporting what occurs in week 45 of this year and in the previous influenza seasons. 4. **Battouili (MHPD):** They did follow up on the GBS. They did look at it for this season and they had 2 cases. They did send an email to Canada Vigilance to follow up and see if they took a report from the company.		
5. Update from BRDD	a) Nathalie sent a quick note to the company (GSK) on their procedures just to let them know and they will put their protocols in place. BRDD will be getting something from the company in the afternoon as to what their plans are. Nothing more was provided from the company. BRDD will keep everyone updated when they know what their plans are. BRDD did verify the quality information that they had in hand and everything was within specification. They verified if anything was out of trend for this lot and nothing in particular was noted. In terms of quality everything seemed to be in good standing. Robert Pless is conducting an investigation.	Robert Pless	**ACTION:** a) NB to send an update regarding the form.

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Agenda Item	Description	Lead	Further Actions or Completed
	Questions: 1. **Jennifer Pennock (PHAC):** a) Do you have a sense of the timeline on when the investigation will be starting? b) Do you happen to know if GSK is planning to inform their international division? Our understanding is that this particular vaccine has been distributed internationally and to see if the manufacturer provided any information on that. Do you have any information on this? **Responded by Robert Pless (BRDD):** **Response to Question 1:** GSK has confirmed that they have initiated the investigation and they will let us know later today of their plans. **Response to Question 2 (Nathalie):** BRDD will follow-up with GSK for a response to this question and to ensure that it is included in their community. 2. **Jennifer Pennock (PHAC):** Can their investigation be shared with this table or is that subject to a confidentiality? **Responded by Nathalie:** It will depend on the content. If it contains propriety information in terms of manufacturing, some of the information may not be shared. However, in terms of adverse reporting, this information can be shared. 3. Question from ?: In terms of the cases that have been associated with this lot and it is		

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	interesting that they have been clustered just in the one jurisdiction and in terms of ruling out other causes, will this information be available over the coming weeks? **Answered by [redacted] (NB):** Yes, they will be shared with GSK and asked if they can do a clinical review. In the 2 serious cases, there was a neurologist involved, more to come. 4. **Question from Robert Pless:** Will you add information about background influence? **Answered by [redacted] (NB):** They were in 3 different public health areas of the province. Two were [redacted] **[redacted] continued with this response to Robert's question:** [redacted] 5. **Question from the chat line:** Any information before vaccination or potential other causes? A question if they had neurological symptoms before their vaccine? **Answered by [redacted] (NB):** [redacted]		

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Agenda Item	Description	Lead	Further Actions or Completed
	[redacted] 6. Question from ???: Are you able to collect any co-morbid conditions such as other infections, concurrent infections? **Answered by [redacted](NB):** We will send updates after the call. 7. Question from ????: A question from the package lot J442P. Is it just the higher level of the packing hierarchy? And this lot would not be recorded. This is not the lot that would be used for the tracking in the inventory systems or the immunization registries would it? **Answered by Nathalie (HC):** The packaging lot is the one that is used for tracking. These two lots are from the same filled container, they are just packaged separately. They were all filled at the same time, they are the same vaccine, but different labels and different lot numbers. 8. Should we be looking for both of these lot numbers in our system? **Answered by Nathalie (HC):** Yes, as they are the same vaccine. • Karin noted that it was put on the CNPHI alert to look for the other lot number.		

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Agenda Item	Description	Lead	Further Actions or Completed
6. Updates from PTs	a) **Comment from Robert Pless:** From what Alan Thom provided, there were only 80,000 doses of J442P and they may have only gone to one province. [redacted] b) **Comment from [redacted] (MB):** [redacted] believes that the doses are correct but the majority of these have actually not been administered but they have been shipped. They are having trouble determining by provider type the total doses administered but the shipment came to MB late to our program and it is going to result in canceling our programs especially in Public Health lead clinics, as they do not have any more supply. They are working on this today. MB denominator will be much lower than the 64,000 administered. c) **Comment from [redacted] (MB):** To share as much information as can be shared concerning the investigation by the manufacturer, the overall natural picture on the signal as well as the investigation with NB. Would appreciate anything that can be shared with everyone. d) **Comment from Jennifer Pennock (PHAC):** In regards to the preferred method of communication, I would suggest that we	ALL	**ACTION:** **a)** A section can be added to the VVWG meeting on November 19, 2020 if PTs have more updates or another meeting can be scheduled on another day if needed. **b)** Jennifer Pennock will check with the Vaccine Supply Team on replacement doses and what the availability is.

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	continue to post CNPHI alerts to the AEFI list and in addition, to send a backup email to the VVWG working group for some redundancy. • [redacted] agreed to Jennifer's suggestions to have both ways to communicate alerts. e) **Question from [redacted] (NB)**: Would we get some replacement doses if these vaccines cannot be used? **Answer from Jennifer Pennock (PHAC):** We would need to raise this question to our Vaccine Supply team at PHAC. Jennifer will ask this question to the Vaccine Supply team to check on availability. f) **Question from [redacted] (NB)**: Would there be any delay in reporting AEFIs regarding with what is happening with COVID? Do we see a clear picture of the actual AEFIs happening across the country? **Answer from Karin:** There is a delay in PHAC receiving the case report forms and Nooshin has sent out a survey asking PTs if it was possible to send in case report forms within 7 days of being notified of an adverse event. Most PTs said that they could send in the reports within this timeline. Nooshin has heard from all PTs and they all agreed to this.		

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Agenda Item	Description	Lead	Further Actions or Completed
7. Next Steps	a) PTs can reach out to PHAC if they need anything.	Amanda/Jennifer	**ACTION:** a) No action
8. Discussion and Questions	a) Questions and discussions were asked throughout each agenda item. Nothing further was added at the end of the meeting.		**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 1, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC** [redacted] **MB:** [redacted] **NB** [redacted] **NS** [redacted] **NT:** [redacted]
NU: [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **QC:** [redacted]
[redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Eugenie Samson, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts, [redacted] Natalia Abraham, [redacted] Oleisa Bissett, [redacted] Angela Sinilaite, **CANVAS:** [redacted]

Regrets:
NL: [redacted] **PE:** [redacted] **CSC:** Samar **Sarkesh, DND:** Marie-Christine Lamontagne **FNIHB:** Kim Daly, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) CAEFISS Analysis

- PHAC provided the most frequently reported AESIs to VVWG on March 25, 2021.
- PHAC sent out an email on March 26, 2021 to VVWG to provide a report on the confidence intervals for serious and non-serious AEFI following COVID-19 vaccination

ii) AstaZeneca hold in EU

- [redacted] will present at next week's VVWG meeting the results of the active surveillance system.
- Health Canada will be sending out questions to VVWG to understand how this is being treated in each jurisdiction and whether the reports that you are collecting and those that are being provided to PHAC would identify the specific version of the vaccine. (Patient information card or second dose card was produced that allows the identification of AstraZeneca versus COVISHIELD)

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoDs from March 12, March 18 and March 25, 2021	a) Agenda was approved with no additional items. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on April 6, 2021.	Amanda Shaw	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on April 6, 2021 to approve and finalize the RoDs from March 12, 18 and 25, 2021. Members were reminded to provide their responses to the following surveys: 1) Preparedness and resources needed to get ready for the influx in AEFIs; and 2) Experience with AstraZeneca. Members who did provide information need to confirm if their information is correct.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The update and the embargoed report will be posted by the end of day on April 1, 2021.	Ashley Weeks	**ACTION:** a) The COVID AEFI report will be sent out at the end of the day on April 1, 2021 to the VVWG members.
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to March 26, 2021. The data presented today includes all AEFIs that were submitted to CAEFISS including those reports that have not been completed or assessed. • One lot number in Moderna [redacted] that seem to have a higher rate of AESIs compared to all other lot numbers in Moderna. PHAC will have a look at this this because it had one of the fewer number of doses distributed 168,600 doses distributed. • BC inquired about the definition of life threatening and thought it was every anaphylaxis report but the numbers are different between what is being reported as anaphylaxis and what is being considered as life	Karin Johnson	**ACTION:** a) PHAC will examine Moderna Lot # [redacted] as this lot has a higher rate of AESIs compared to other lot numbers with Moderna. b) Karin will clarify for BC the anaphylaxis and the life threatening rates that have been reported. This will be provided next week. c) PHAC will provide the top 3, 5 or 10 lot numbers of each vaccine (COVISHIELD,

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	threatening. In addition, BC noted that the total serious does not include all the anaphylaxis cases, which they thought were all life threatening. - Karin noted that it could be the coding that has been done in CAEFISS. PHAC is currently going through a QA in CAEFISS to ensure that all anaphylaxis is recorded as life threatening. • AB inquired if it would be possible for PHAC to look at the top 10 lot numbers for each of Moderna, Pfizer, and COVISHIELD and present a table of the top 3, 5 or 10 lot numbers of each vaccine that that we are seeing the most AEFIs with. PHAC has agreed to provide this at next week's meeting.		Moderna, and Pfizer) that we are seeing the most AEFIs.
4. CANVAS Update	a) [redacted] provided an update on the CANVAS weekly report. The CANVAS weekly report presentation was shared with VVWG members. • BC inquired about comparison to control group rates. - [redacted] noted that yes, they are collecting controls. They are still working on merging. She is hoping that they will have control data for VVWG next week. b) [redacted] provided a presentation on Coagulation rates report. • It was noted that there is a higher rate among women than men and independent of the vaccine that they are getting. • Dose 2 data is limited • Amanda inquired if they get the details to be able to split out what the coagulation problem is. - [redacted] noted that no, they cannot.	[redacted]	**ACTION:** a [redacted] will share the CANVAS weekly report to VVWG Secretariat weekly to circulate to the members.
5. AstraZeneca Update - NACI Statement - Health Canada Statement - International Updates	a) Joseline Zafack provided a summary of the NACI statement that was released this week. • On March 29, 2021, NACI released a rapid response recommending that AstraZeneca should not be used in adults under 55 years of age while the safety signal of	Amanda Shaw Joseline Zafack Jhona Rose	**ACTION:** a) PHAC has shared the link the to NACI statement with VVVWG: NACI rapid response: https://www.canada.ca/en/public-

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	Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) following vaccination with AstraZeneca COVID-19 vaccine is investigated further. • The rationale of this decision was based on the data that they currently have which is incomplete at this stage and NACI is currently monitoring on what is forthcoming. • The current data showed that in younger adults that complications from COVID-19 or the risk of dying is quite low but an adverse event that occurred in Europe following the receipt of the AstraZeneca vaccine, the cases identified have been primarily women under the age of 55 although some cases in men have also been reported. The rate of fatality was approximately 40%. The risk benefit balance was not in favour of younger adults therefore, NACI recommended that AstraZeneca should only be administered to adults 55 and older. • NACI is closely monitoring the information that is coming from Europe and other countries, and based on the evidence, NACI will update the recommendation if needed. • EMA released a statement on March 31, 2021 that they have not changed their recommendation regarding the use of AstraZeneca. They are going to release different recommendation during the preliminary meeting that will be held from April 6-9, 2021. b) Jhona Rose provided a summary of the Health Canada Statement that was released this week. • As of last week, HC put forward labelling updates for the product monograph for COVISHIELD, and AstraZeneca • A public advisory was done from March 11 and March 18, 2021		health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommended-use-astrazeneca-covid-19-vaccine-younger-adults.html b) HC has shared the EMA preliminary assessment link with VWG: https://www.ema.europa.eu/en/news/astrazeneca-covid-19-vaccine-review-very-rare-cases-unusual-blood-clots-continues

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	• HC requested the updated Risk Management Plan which contains undescribed post marketing activities • HC also requested additional cumulative assessment of the adverse events for the company to assess and summarize. HC also imposed terms and conditions. • HC will be observing the EMA meeting taking place from April 6-9, 2021. • EMA released their new statement about their assessment to date. This is available on their website.		
6. Thrombolic events in CAEFISS - CAEFISS case definition updates - BC/SPECA definition and algorithm	a) Natalia provided a presentation on CAEFISS case definitions – Thrombosis and Thrombocytopenia cases. Natalia will share a copy of her power point presentation after the meeting. b [redacted] provided a presentation on Brighton Collaboration/SPECA definition and algorithm. • A word document will be provided and posted on CNPHI soon. • Susanna Ogunnaike-Cooke from PHAC inquired about when this document will be finalized. - [redacted] noted that it would be another 4-6 weeks before this is finalized. Currently, the draft is being shared and it can be used. • MB inquired about level 4 and level 5. - MB will send the question in detail to the VVWG email inbox and [redacted] will provide a response via email due to time constraints at the meeting.	Natalia Abraham [redacted]	**ACTION:** a) Natalia will share a copy of her power point presentation to VVWG members after the meeting. b) MB will send their detailed question to the VVWG inbox and [redacted] will respond via email.
7. Background Rates Update - Thrombolic events	a) Sarah provided a presentation on the Background rates. The power point presentation will be shared with VVWG after the meeting. • [redacted] inquired if they would be able to do a breakout by age group. - Sarah noted that yes they do plan to do a breakout by age group and sex. Once they are ready, they do plan to put them on CNPHI. They plan to add potential	Sarah Spruin	**ACTION:** a) The Background rates power point presentation will be shared with the VVWG members after the meeting.

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Agenda Item	Description	Lead	Further Actions or Completed
	subgroups, for stroke, and a broader definition for thrombocytopenia. They are going to update the anaphylaxis rates with the current methodology, bells palsy, GBS, etc. • [redacted] from IMPACT inquired if PHAC would be able to get background rates from 2020. Some of the events have been seen as complications of COVID-19. Are you able to get background rates for cerebral venous since thrombosis? Also, interesting to look by sex. - Yes, PHAC is able to get the 2020 data but it might not be fully complete as the provinces can continue to update their data. PHAC has not been able to work on this yet, as it can take some time but it can be done. - Sarah will add cerebral venous to their list. She will take it back to the working group and the working group will work on a definition and then add it to the background rates.		
8. Roundtable - Update on AZ use in PTs - Updates on thrombotic cases in PTs - Response to survey on preparedness and needs	a) This item was deferred to the next week's VVWG call.	ALL	**ACTION:** a) The roundtable items will be discussed at next week's VVWG meeting.
9. Confirm Next Call	a) Next call: April 8, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 8, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Federal Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted]
NL: [redacted] **NT:** [redacted] **ON: (MOH)** [redacted] **PHO):** [redacted]
PE: [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar **Sarkesh, DND:** Marie-Christine Lamontagne **FNIHB:** Kim Daly, **IMPACT** [redacted] **MHPD:** Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Eugenie Samson, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts, Dr. Barb Law, Natalia Abraham, [redacted] Oleisa Bissett, Natalie Dayneka, Angela Sinilaite, **CANVAS:** [redacted]

Regrets:
NU: [redacted] **QC:** [redacted] **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   - **i) Introduction, roll call, agenda, minutes from last meeting**
     - Some member responses have been received for the two surveys but responses are still pending
   - **ii) CAEFISS Analysis**
     - PHAC examined Moderna [redacted]
     - Karin provided clarification to BC about the anaphylaxis and life threatening rates that have been reported.
     - Karin was not able to provide the top 3 to 5 lot numbers of each vaccine (COVISHIELD, Moderna, and Pfizer) that are seeing the highest rate of AEFIS. This will be sent out on April 9, 2021 along with the slide presentation to VVWG. Karin will highlight the lots that have the highest rates of AEFIs on the document.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD April 1, 2021	a) Agenda was approved with no additional items. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on April 9, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on April 9, 2021 to approve and finalize the RoD.
2. Thrombotic Events Presentation	a) Bryna Warshawsky provided a presentation on "Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)".	Bryna Warshawsky	**ACTION:** a) Bryna will share her presentation with VVWG after the meeting
3. Weekly On-line COVID AEFI Report	a) Allison provided a brief summary of the Weekly on-line COVID AEFI Report. The update and the embargoed report will be posted by the end of day on April 9, 2021.	Allison Yeung	**ACTION:** a) No action
4. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to April 9, 2021. There has not been any changes from last week.	Karin Johnson	**ACTION:** a) Karin will provide the top 3 to 5 lot numbers that have the highest rate of AEFIs. This will be sent out on April 9, 2021 with the slide presentation to VVWG. The lots that have the highest rates of AEFIs will be highlighted in the document.
5. CANVAS Update	a) [redacted] provided an update and presentation on the results from individuals with a previous COVID-19 infection.	[redacted]	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
6. Thrombotic Events - CAEFISS - Canada Vigilance - International news	a) Natalia provided an update on the cases submitted to CAEFISS. Natalia's presentation was provided to VVWG members prior to the start of the meeting. b) Jhona Rose provided an update on Canada Vigilance and international news. • HC has been following the EMA's assessment closely • EMA released their statement regarding their result of their assessment. Similarly, WHO, MHRA in the UK, Australia, have all released a statement. • Reviews are expected to be completed in a shorter period.	Natalia Abraham Jhona Rose	**ACTION:** a) No action b) No action

7. Data Sharing Proposal	a) Susanna provided a presentation on the Data Sharing Proposal.
	• The pandemic has raised the need for sharing data with Health Canada and manufacturers (who have a responsibility to track product safety but don't have access to all the data that they need)
	• The Data Sharing proposal was brought forward to SAC last week. The proposal was to post a limited line list of the cases reported to PHAC in CAEFISS with just 11 variables (11 variables have been identified, none of which are direct or indirectly identifiable). [redacted]
	• The proposal put forward to SAC was:
	  ○ Posting online (monthly)
	  ○ Accessible to pharmacovigilance partners (i.e. manufacturers, etc.)
	• PHAC is awaiting for input written responses from SAC members and PHAC did receive some questions at the meeting.
	• PHAC is waiting for input from SAC and VVWG members.
		Susanna Ogunnaike-Cooke	**ACTION:**
			a) No action

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Agenda Item	Description	Lead	Further Actions or Completed

	• Overall the response has been positive however, The following concerns have been shared:
	  ○ If information is released for public access will it be misinterpreted
	  ○ What resources will the PTs need (i.e. Privacy Impact Assessment, etc.)
	  ○ Will the public be more resistant to sharing their information		

8. Vaccination Technique	a) Nooshin discussed the proper vaccination technique with PTs. Nooshin noted to VVWG about potential cases about arm and shoulder pain. Patients exhibit limited range of motion when the vaccine is administered in the upper arm is given too high • First report was received last week following COVID vaccination. • Recommending possible retraining health care providers in the field to help the vaccination campaign • Nooshin has asked that this information be communicated to those in the field to prevent this from happening • This is not considered to be a serious event	Nooshin Ahmadipour	**ACTION:** a) No action
8. Roundtable	a) This has been deferred to next week's meeting.	ALL	**ACTION:** a) This has been deferred to next week's VVWG meeting (April 15, 2021).
9. Confirm Next Call	a) Next call: April 15, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Monday, April 12, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] Provincial Co-Chair), [redacted] **BC:** [redacted] **MB:** [redacted] **NB** [redacted] **NS:** [redacted]
[redacted] **NL:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] **(PHO)** [redacted]
[redacted] **PE:** [redacted] **QC:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar **Sarkesh, DND:** Marie-Christine Lamontagne **FNIHB:** Kim Daly, **MHPD:** Jhona Rose, Kathleen Eng, Battouli Said Salim, Angel Noble, Sophie Sommerer, **RCMP:** Roxanne Tauvette;

Observers/Presenters in Attendance:
Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Kimberley Hutchings, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts [redacted] Natalia Abraham, Oleisa Bissett, [redacted] Catherine Dickson, Jean Nkanza, Kaitlin Patterson, Shikha Saxena, April Killikelly, Ashley Weeks, Erica Loughlin, [redacted] **CANVAS:** [redacted]

Regrets:
IMPACT: [redacted]

Agenda Item	Description	Lead	Further Actions or Completed
1. Welcome	a) Susanna welcomed everyone to the meeting. There are two main objectives to the meeting: 1. Update on thrombosis and thrombocytopenia syndrome in Canada 2. **Case Definition**: Our senior management and Special Advisory Committee (SAC) has asked for a presentation at tomorrow's SAC meeting on case definitions (related to thrombosis and thrombocytopenia syndrome) and for a proposed approach for testing suspected cases.	Susanna Ogunnaike-Cooke	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	This meeting is being used as a ad-hoc meeting to share our draft information and for a proposed approach for testing suspected cases.		
2. Review of Thrombosis/Thrombocytopenia case definitions and case management proposal	a) Natalia Abraham provided a presentation on "**Thrombosis and Thrombocytopenia after COVID-19 vaccination in Canada.**" • PHAC was seeking feedback, input and or recommendations from VVWG members regarding the case definition that will be presented to SAC April 13, 2021. • [redacted] inquired about how these cases are being treated in hospital if they present without thrombocytopenia. What will be the clinical management of these cases will be. How can we confirm these cases? • [redacted] noted what would be useful when jurisdictions report these types of cases to the Agency is a clear list of data elements that PHAC would like jurisdictions to report. ▪ PHAC will look into key data elements required in order for PHAC to conduct an assessment of potential cases submitted into CAEFISS.	Natalia Abraham	**ACTION:** a) Natalia will share her presentation with VVWG after feedback is received from VVWG members and after it is presented to SAC on April 13, 2021. b) PHAC will look into key data elements required in order for PHAC to conduct an assessment of potential cases submitted into CAEFISS.
3. Discussion	a) A brief discussion occurred regarding thrombosis and thrombocytopenia and the case definition being presented at the SAC meeting on April 13, 2021.	All	**ACTION:** a) No action
4. Roundtable	a) No items were discussed during the roundtable discussion.	All	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 15, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB [redacted] (Provincial Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (PHO):** [redacted] **QC:** [redacted] **PE:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne **FNIHB:** Kim Daly, **IMPACT** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Angela Noble,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Eugenie Samson, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Jamal Ahmadian-Yazdi, Karen C. Roberts, [redacted] Natalia Abraham, [redacted] Christina Jensen, Megan Jackman, Jean Nkanza, Erica Tice, **CANVAS:** [redacted]

Regrets:
ON: (MOH) [redacted] **NL** [redacted] **CSC:** Samar **Sarkesh, RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) CAEFISS Analysis

- Karin provided the top 3 lot numbers that have the highest rate of AEFIs. This was sent out on April 9, 2021 with the slide presentation to VVWG. The lots that have the highest rates of AEFIs have been highlighted in the document.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with one additional item to be added to the roundtable: what are the policies and practices of each province and territory on reporting the non-serious common AEFIs such as, vaccination site reactions.	Amanda Shaw	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD April 8, 2021 and April 12, 2021	b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on April 16, 2021.		end of day on April 16, 2021 to approve and finalize the RoD. c) A reminder email will be sent out to members to provide their responses to the following surveys: 1. Preparedness and resources needed to get ready for the influx in AEFIs; and 2. Experience with AstraZeneca. Members who did provide information need to confirm if their information is correct.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The update and the embargoed report will be posted by the end of day on April 16, 2021.	Ashley Weeks	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to April 9, 2021. There has not been any changes from last week. • Karin asked PTs if they would be interested if PHAC would report serious and non-serious AEFIs by province and territory (Total count and rate of serious and non-serious by Province and Territory). Would PTs be interested in seeing this in VVWG? ▪ Some PTs responded (MB, NB, NS) and are interested ▪ PTs were asked to send their comments or concerns to Amanda and Karin.	Karin Johnson	**ACTION:** a) PHAC will send out an email with a breakdown of the top 3 serious AEFI rates by lot number. b) Members can send their comments or concerns to Amanda Shaw and/or Karin Johnson regarding interest in PHAC reporting serious and non-serious AEFIs by Province and Territory.
4. CANVAS Update	a) [redacted] provided an update on CANVAS. A weekly CANVAS report will be posted on CNPHI every Friday.	[redacted]	**ACTION:** a) The CANVAS weekly report will be posted on CNPHI every Friday.

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Agenda Item	Description	Lead	Further Actions or Completed
5. Advisory Committee on Causality Assessment (ACCA)	a) [redacted] provided a presentation on the Advisory Committee on Causality Assessment (ACCA).	[redacted]	**ACTION:** a) Members can provide their comments/input to [redacted] via email. [redacted] will share her presentation with VVWG on CNPHI after the meeting.
6. AstraZeneca Update - CAEFISS - Canada Vigilance - International Rates - Background rates update	a) Natalia provided an update on the draft case finding definition. The draft case finding definition (Thrombosis and Thrombocytopenia) was published by Brighton Collaboration last weekend. [redacted] received some feedback from CIC and she also provided a presentation to the Special Advisory Committee (SAC). [redacted] provided an update on what is going on with the draft interim case finding definitions for thrombosis with thrombocytopenia. There are significant changes that are in the works and may possibly be released on April 16, 2021. b) Jhona provided a Health Canada update regarding the statement that was released on April 14, 2021. • The notice was regarding the labelling changes in the Canadian product monograph. • HC is expecting additional documents coming from the company/manufacturer next week, which includes the additional risk minimization activities and additional studies. • HC is also expecting the Summary Safety Report that will summarize additional data that they might have on these adverse events. • A summary of HC safety review is expected to be released soon.		**ACTION:** a) No action b) No action c) [redacted] will share with VVWG after the meeting a paper from the University of Oxford

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Agenda Item	Description	Lead	Further Actions or Completed
	c) Sarah provided an update on the background rates. ▪ BC inquired on how PHAC will be using this for safety Surveillance. - This is being used by the NACI Safety Working Group. - PHAC will eventually publish these rates - Background rates will be very helpful for ACCA review once it is established		
8. Roundtable	a) This has been deferred to next week's VVWG meeting (April 22, 2021).	ALL	**ACTION:** a) This has been deferred to next week's VVWG meeting.
9. Confirm Next Call	a) Next call: April 22, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 22, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC:** [redacted] **NL** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted]
[redacted] **ON: (MOH** [redacted] **(PHO):** [redacted] (MOH), [redacted] **PE:** [redacted]
SK: [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne **FNIHB:** Melanie Knight, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Angela Noble, Sophie Sommerer

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Jamal Ahmadian-Yazdi, Karen C. Roberts, [redacted] Natalia Abraham, [redacted] Megan Jackman, Jean Nkanza, Erica Tice, **CANVAS:** [redacted]

Regrets:
MB: [redacted] **NB:** [redacted] **QC:** [redacted] **CSC:** Samar **Sarkesh, IMPACT:** [redacted] **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) Introduction, roll call, agenda, minutes from last meeting

Most members provided responses to the two surveys; a) Preparedness and resources needed to get ready for the influx in AEFIs; and b) Experience with AstraZeneca. Members who did provide information need to confirm if their information is correct.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD April 15, 2021	a) Agenda was approved. One additional agenda item was added, AEFI Grant Resources Update. • Susanna provided a brief update on the AEFI Grant Resources • A questionnaire was submitted at VVWG to PTs requesting information regarding the resources required. The 3 categories of resources that are required by PTs are: o Financial resources o Human resources o IT resources (tools/support from PHAC to provide) • Financial/Human Resources have been briefed up to senior management at PHAC. o Immunization program fund o Fall economic update funding • PHAC will contact those who indicated a need next week to get specifics and how PHAC can move things forward. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on April 23, 2021.	[redacted]	**ACTION:** a) An additional agenda item was added, AEFI Grant Resources Update. • PTs can send an email to PHAC if they still require assistance b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on April 23, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to April 16, 2021. The update and the embargoed report will be posted by the end of day on April 23, 2021.	Ashley Weeks/Allison Yeung	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to April 16, 2021.	Karin Johnson	**ACTION:** a) The analysis report will be sent out to jurisdictions by April 26, 2021 along with the table of PT rates and number of reports submitted.

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Agenda Item	Description	Lead	Further Actions or Completed
			b) PHAC will present at next week's VVWG meeting the local reactions of the second dose of MRNA vaccines (by severity).
4. CANVAS Update	a [redacted] provided an update on CANVAS up to April 14, 2021. The report has been posted on CNPHI.	[redacted]	**ACTION:** a) No action
5. AstraZeneca Update - Thromboembolic cases in CAEFISS/CVD - Updated case finding definition - Early heads up to PHAC - International regulatory updates	a) Natalia provided a presentation on **Thrombocytopenia Thrombosis Syndrome (TTS) – Interim Case Finding Definition for Passive Surveillance.** • Natalia has asked that members respond to the following 5 questions by April 26, 2021: 1. Should we extend the timing of the onset of symptom from within 28 days to 6 weeks? 2. Should anti-PF4 status be a subtype of a confirmed TTS case definition? 3. Should possible and probable case definitions be based on Brighton Collaboration levels of certainty of thrombosis or thromboembolism, or do other criteria take precedence in the Canadian context? 4. Should a possible case definition additionally include thrombocytopenia with or without signs of thrombosis? 5. What case definitions have already been developed in your jurisdiction? b) Amanda reiterated to members that it is very helpful when provinces gives PHAC a heads up for any cases on thrombosis with thrombocytopenia syndrome case. PHAC does not want to miss any of these cases. c) Sophie Sommerer provided an International regulatory update and a Health Canada update. • The UK is publishing an update on a weekly basis. They continue to see these cases being reported.	Natalia Abraham Amanda Shaw Jhona Rose (HC)	**ACTION:** a) Natalia's presentation will be shared with VVWG after the meeting. • Members are to provide their responses to the 5 questions by April 26, 2021. It was noted that PTs may need more time to respond. b) No action c) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	The cases are more spread out by age and sex than previously determined. The mortality rate has decreased. • Australia has been posting updates as well as they have been identifying and confirming cases in their jurisdiction following immunization with the AstraZeneca vaccination • Europe has released their review report with their previous findings • HC Summary Safety Case review has been completed • AstraZeneca has proposed additional changes to the product monograph and it is under review by HC • Jansen vaccine cases have been identified in the US o European Medicine Agency also implemented changes to their product labelling and have prepared a risk communication that will be disseminated in Europe next week o HC is looking at the information of post market cases o HC is working to update the product monograph an risk communication for next week		
6. Updated AEFI Form	a) Karen provided an update on the AEFI form. Some new fields have been added: 1. Racial background and Indigenous Identity 2. Thrombocytopenia with thrombosis syndrome 3. Modifications to accommodate COVID-arm 4. COVID-19 Annex in User Guide (this is under final review) – Provide additional detail on COVID-10 AESI including temporal reporting criteria • Karen noted that they are hoping to have this posted by June 2021. • PHAC recommends that all AEFIs be reported to the CAEFISS system.	Karen C. Roberts	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
7. Roundtable - What are the policies and practices of each province and territory on reporting the non-serious common AEFIs for COVID Vaccines such as, vaccination site reactions?	a) Please see Appendix A for a summary of responses from jurisdictions from the roundtable discussion.	ALL	**ACTION:** a) No action
8. Confirm Next Call	a) Next call: April 29, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, April 29, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] Provincial Co-Chair), **BC** [redacted] **MB:** [redacted] **NB** [redacted] **NL:** [redacted] **NS:** [redacted]
NU: [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **PE** [redacted]
SK: [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne **FNIHB:** Melanie Knight, **MHPD:** Jhona Rose, Battouli Said Salim, Angela Noble, Sophie Sommerer, Tonja Strothart

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Jamal Ahmadian-Yazdi, Karen C. Roberts, [redacted] Natalia Abraham, [redacted] Amrit Boese Christina Jensen, Erica Loughlin, Nora MacLeod- Glover, Jean Nkanza, Megan Jackman Shihka Saxena, Samantha Parker, Olesia Bissett, **CANVAS:** [redacted]

Regrets:
NT: [redacted] **QC:** [redacted] **CSC:** Samar Sarkesh, **IMPACT:** [redacted] **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) CAEFISS Analysis

PHAC will present at the April 29, 2021 VVWG meeting the local reactions of the second dose of MRNA vaccines (by severity).

ii) AstraZeneca Update

Some Members provided their responses to the five questions on **Thrombocytopenia Thrombosis Syndrome (TTS) – Interim Case Finding Definition for Passive Surveillance.** A few PTs have requested additional time to provide their input. PHAC has asked that responses be provided to PHAC by April 30, 2021.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD April 22, 2021	a) Agenda was approved with no additional items. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on April 30, 2021. c) Meeting invitations are being set up to discuss PT resource requirements with Susanna Ogunnaike-Cooke.	Amanda Shaw	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on April 30, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Allison provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to April 23, 2021. The update and the embargoed report will be posted on April 30, 2021 by the end of the day.	Ashley Weeks/Allison Yeung	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to April 23, 2021. • Karin noted that the format of the weekly updates have changed. The updates will address questions raised at meetings and by email by members. • AEFI reports are now being reported by jurisdictions	Karin Johnson	**ACTION:** a) Karin will share the CAEFISS Analysis on CNPHI after the meeting.
4. CANVAS Update	a) [redacted] provided an update on CANVAS up to April 28, 2021. The report has been posted to CNPHI.	[redacted]	**ACTION:** a) No action
5. Myocarditis summary - Cases in Canada	a) Amanda provided a presentation on Myocarditis following Pfizer vaccine.	Amanda Shaw Jhona Rose (HC)	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed

- Summary of international findings	• This week there have been reports in the media about a number of myocarditis reports in certain countries, in particular in young males following the Pfizer vaccine.
	• The first reports came from Israel.
	• An assessment was done by PHAC. In total, we have 8 cases (6 females and 2 males) in CAEFISS/Canada Vigilance. The age range 20 -53.
	  ○ 5 following dose 1
	  ○ 3 following dose 2
	  ○ Time of onset is 5 hours to 21 days
	  ○ This is out of 7 million doses in Canada
	
	b) Jhona provided a summary of the international findings
	• A Pharmacovigilance meeting was held on April 28, 2021. HC brought their results forward to this meeting.
	• The cases occurring in Israel are in males between the ages of 16-30.
	• HC examined all the databases that they have access to
	• Manufacturer monthly safety reports are regularly reviewed.
	• There is ongoing monitoring of this event
	• Another meeting will be held next week
	• Tonya (HC) noted that myocarditis as a medical diagnosis is most likely of exclusion and for the most part, the epidemiology of it is not well understood and there is no good information about background rates. This is due to the presentation with non-specific or mild signs and symptoms. There is no easy non-invasive test to diagnose it.
			b) No action

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Agenda Item	Description	Lead	Further Actions or Completed
6. AstraZeneca Update - TTS case definition update - Summary of TTS cases in Canada - Summary of international findings	a) Natalia provided an update on **Thrombocytopenia Thrombosis Syndrome (TTS)** definition. • Natalia noted that the results so far that have been received from the TTS survey questions are in align with the Brighton Case definition • Jurisdictions have been asked to provide their responses to the TTS survey by April 30, 2021. • Currently have 12 confirmed cases (thrombosis with thrombocytopenia) - 8 have a positive antigen PF4; 4 unknown status; 1 negative b) Sophie Sommerer provided an International regulatory update and a Health Canada update. • Health Canada finalized another update for the product monograph/labelling (COVISHIELD, AstraZeneca, Janssen). This was posted on the HC website on April 26, 2021. • Janssen received some post market reports. • 8 post market reports were available but 15 cases were described • International bodies are continuing to monitor and update these events as they evolve ○ UK yellow report updates weekly ○ Australia updates as they get cases of TTS ○ FDA and CDC examining cases related to Janssen	Natalia Abraham Jhona Rose (HC)	**ACTION:** a) Jurisdictions have been asked to complete the TTS case definition survey by COB on Friday, April 30, 2021, as the results will be presented at next week's SAC meeting. b) No action
7. NACI update on AZ recommendations	a) Kelsey provided a presentation on the National Advisory Committee on Immunization (NACI): Updated Benefit-risk assessment for recommendation on the use of AstraZeneca COVID-19 vaccine. • [redacted]	Kelsey Young	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	• Potential benefits - NACI looked at ICU admissions and deaths prevented by early AstraZeneca instead of waiting until age-based mRNA vaccine • Wait times have now changed but so has the availability of the mRNA vaccines. • Epidemiology in regions must be considered as well. • NACI amended their age recommendation for AstraZeneca to individuals 30 years of age and older		
7. Roundtable - PT observations of AEFIs with AZ/COVISHIELD	a) This item has been deferred to next week's meeting.	ALL	**ACTION:** a) This item has been deferred to next week's meeting.
8. Confirm Next Call	a) Next call: May 6, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, February 4, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NL:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU** [redacted] **ON (MOH):** [redacted] **ON (PHO):** [redacted] **PE:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne, **FNIHB:** Kim Daly, **IMPACT:** [redacted] **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Saundra Houle, Karin Johnson, Catherine E. Dickson, Carmen Salinas, Sara Spruin, Christina Jensen, Emily Wahl, [redacted] Joseline Zafack, Alexander Szumillas, Jasminka Draca, Jocelyn Bougie, Andrew Atabe,-Jamal Ahmadian-Yazdi, Shannon Lewis,

Regrets:
QC: [redacted] **CSC:** Samar Sarkesh, [redacted] (CANVASS), **RCMP:** Natalie Toupin

ACTION ITEMS

1. **Action Item Updates**
   i) **Weekly COVID AEFI Report**
   - The Weekly COVID AEFI report did not go live on Friday, January 29, 2021. It was delayed due to death reporting and wording surrounding this issue.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of January 28, 2021 RoD	a) Agenda was approved. b) RoD was approved. No changes were made.	[redacted]	**ACTION:** a) No action b) No action

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Agenda Item	Description	Lead	Further Actions or Completed
2. Expedited Reporting Update a) Flu b) COVID-19	a) Eugenie provided a brief summary of the influenza counts for week 4. b) Theresa provided a brief summary of the COVID-19 vaccine for week 4.	Eugenie Samson/Theresa Procter	**ACTION:** a) No action **b)** Catherine Dickson will share with the VVWG Secretariat links to COVID-19 safety updates and reports from other countries after the meeting.
3. Weekly COVID AEFI Report	a) A brief summary of the weekly COVID AEFI report could not be provided today. The release of the weekly report was delayed on Friday, January 29, 2021 due to death reporting and wording surrounding this issue.	Karin Johnson	**ACTION:** a) An Embargo copy will be sent out to VVWG once final approvals are received from PHAC, HC and Communications.
4. Delayed onset vaccination site reaction and lymphadenopathy following COVID-19 vaccination	a) Nooshin presented information on the delayed onset vaccination site reaction which was based on a question from one of the jurisdictions and from the public (local redness, tenderness and swelling starting a few days post immunization) - Based on the reports submitted by CAEFISS, the majority are reported following the Moderna vaccine within a few days. - These sorts of reactions are described in the **Moderna efficacy and safety Phase 3 study** from December 2020. This has been called a delayed reaction with Moderna's vaccine and the Media has called this **"COVID arm"**	Nooshin Ahmadipour	**ACTION:** a) This agenda item will be further discussed at next week's VVWG meeting (February 11, 2021)
5. Roundtable ▪ **Reporting deaths following vaccination** - What is each PT doing? - Do PTs report all deaths following vaccine, or only those ones they determine to be casually related? - Which PTs are currently reporting AEFIs publically?	a) PHAC asked jurisdictions to provide their responses on how they report deaths following vaccination and if AEFIs are reported publically. The responses from each jurisdiction is listed below:	All	**ACTION:** a) No action b) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	AB [redacted] **BC** ▪ Only report deaths with no other clear cause within 30 days ▪ Not publically reporting AEFIs but may in the future **MB** ▪ MB reports deaths that occur within 30 days of vaccination ▪ The antecedent AEFI or medical condition that led to the demise itself is reportable. If no antecedent AEFI is identified, the death itself is the AEFI and should be reported as such if occurred within 30 days. **NB** ▪ Agrees with MB; reports deaths if AEFI meets criteria and results in death (even if no causality) ▪ Will confirm that this is the case for COVID ▪ Not currently reporting AEFIs publically but developing a dashboard **NL** ▪ N/A **NS** ▪ NS does not report an AEFI death to PHAC until a full investigation has been completed. ▪ Any death of a vaccine recipient temporally linked (within one month) to immunization, where no other clear cause of death can be established must be reported to the province. Also, fetal deaths that occur following		

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ATIA - 13(1)(c)

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Agenda Item	Description	Lead	Further Actions or Completed
	immunization of a pregnant woman and deaths in infants diagnosed as Sudden Infant Death Syndrome when the investigation has concluded. ▪ NS only reports AEFI numbers annually within their Annual Notifiable Diseased Reports which are available on their public website **NU** ▪ Report all deaths within 30 days ▪ Not publically reporting AEFIs **NWT** ▪ Following PHACs preference and reporting all deaths within 30 days ▪ Not publically reporting AEFIs **ON** ▪ ON only includes reports of deaths that meet their provincial surveillance definition for a confirmed case which does not include those death that have been attributed to another cause of death through a formal process and they do not include reports of deaths that are currently under review/investigation. ▪ [redacted] ▪ They do have a public report (weekly summary on website) **QC** ▪ Deaths are reported where there is clearly no other cause that can explain the issue ▪ Reports will be publically available as of February 11, 2021 **PEI** ▪ PEI Investigates all deaths and only report those determined causally related ▪ Not publically reporting AEFIs **SK** ▪ Reporting all deaths within 30 days		

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ Not publically reporting AEFIs **YT** ▪ Report deaths causally related ▪ Not publically reporting AEFIs		
6. Confirm Next Call	a) Next call: February 11, 2021 (1:30 – 2:30 EDT)	[redacted]	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, February 11, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **PE:** [redacted] **QC:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh **DND:** Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Saundra Houle, Karin Johnson, Catherine E. Dickson, Carmen Salinas, Sara Spruin, Christina Jensen, Emily Wahl [redacted] Joseline Zafack, Alexander Szumillas, Jasminka Draca, Jocelyn Bougie, Andrew Atabe, Jamal Ahmadian-Yazdi, Shannon Lewis [redacted] (CANVASS), [redacted] Presenter - McGill University), [redacted] (Observer – McGill University), [redacted] (Observer – McGill University)

Regrets:
NL: [redacted] **FNIHB:** Kim Daly,

ACTION ITEMS

1. **Action Item Updates**
   - **i) Expedited Reporting Update**
     - Catherine Dickson shared with the VVWG Secretariat links to COVID-19 safety updates and reports from other countries after the meeting. This was distributed to VVWG members on the same day.
   - **ii) Weekly COVID AEFI Report**
     - An Embargo copy was sent out to VVWG.
   - **iii) Delayed onset of vaccination site reaction and lymphadenopathy following COVID-19 vaccination**
     - This discussion was supposed to be carried over into today's meeting but it will be addressed at next week's VVWG meeting due to a heavy agenda.

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iv) Roundtable Discussion – Reporting Deaths following vaccination

- PTs who did not provide a response regarding death reporting and public AEFI reporting need to follow up with PHAC via email.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of February 4, 2021 RoD	a) Agenda was approved. b) RoD needs some minor corrections.	Amanda Shaw	**ACTION:** a) Delayed onset of vaccination site reaction and lymphadenopathy following COVID-19 vaccination will be addressed at next week's VVWG meeting b) MB will provide via email this week the proper response regarding death reporting and public AEFI reporting for MB. PTs who did not provide a response regarding death reporting and public AEFI reporting need to follow up with PHAC via email.
2. Presentation: Vaccine Surveillance Reference Group/Covid-19 Immunity Task Force	a) A presentation was provided by [redacted] from McGill University on **"Vaccine Surveillance Reference Group/COVID-19 Immunity Task Force"** ▪ Vaccine Surveillance Reference Group (VSRG) was created to track vaccine effectiveness and safety in Canada ▪ VSRG reports to the President of PHAC ▪ [redacted] ▪ [redacted]	[redacted] McGill University	**ACTION:** **a)** A copy of [redacted] presentation will be distributed to VVWG. If anyone needs to contact [redacted] his email is [redacted]@mcgill.ca [redacted] will be presenting at the CIC meeting on February 16, 2021.

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ATIA - 13(1)(c) ATIA-14(a)

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ [redacted] inquired about the requirements for funding reporting. Is it a grant? - There will be some reporting requirements however; COVID-19 Immunity Task Force (CITF) can provide resources to assist with the reporting. Results will need to be shared across the country (data sharing platform) which is a requirement.		
2. Expedited Reporting Update a) Flu b) COVID-19	a) Eugenie provided a brief summary of the influenza counts for week 5. b) Theresa provided a brief summary of the COVID-19 vaccine for week 5. - Moderna has a higher reporting rate of AEFIs - Anaphylaxis rate is much higher than what is being reported in the US - A discussion took place regarding the difference between allergic vs anaphylaxis Before reclassifying cases that do not meet the criteria, PTs will be provided a list of cases that have been flagged after medical review. PHAC will follow up with the PTs. If PTs are in agreement, the report will be updated (allergic from anaphylaxis)	Eugenie Samson/Theresa Procter	**ACTION:** a) No action b) No action
3. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the Weekly COVID AEFI Report. • BC noted that the wording on the last page of the report on deaths should be amended "..[redacted]" as it is not clear and difficult to interpret. PHAC will	Ashley Weeks	**ACTION:** a) On Friday, February 12, 2021, PHAC will be posting in the Adverse Events section; the most frequently reported adverse events. The majority are mostly vaccination site reactions.

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Agenda Item	Description	Lead	Further Actions or Completed
	look into this and provide clarity to the wording.		b) On the last page of the report on deaths, the second bullet, PHAC will provide clarity to the wording.
4. Background rates	a) Sarah provided an update on the Background rates. • PHAC is working with the Background Rates Working Group to start obtaining some background rates. They started with anaphylaxis and Bell's Palsy • Rates were calculated using Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) PHAC does not have data on QC as they have there own system in place. • Physician billing data was not included due to the fact that PHAC does not have access to it • There are three definitions for anaphylaxis: 1. Anaphylaxis due to vaccination or other serum and not otherwise classified 2. All codes related to anaphylaxis 3. All codes relating to anaphylaxis and allergic reactions • Rates currently observed for Bell's Palsy are low (not a concern at this time) • Anaphylaxis rates should be monitored • Definition 2 for anaphylaxis is more in line with Europe whereas Definition 1 is in line with the US.	Sarah Spruin	**ACTION:** a) No action
5. Alterations to the Anaphylaxis Brighton Collaboration case definition	a) This agenda item will be moved to next week's VVWG meeting (February 18, 2021).	[redacted]	**ACTION:** a) Moved to next week's VVWG meeting (February 18, 2021)

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Agenda Item	Description	Lead	Further Actions or Completed
6. Roundtable	a) No items to discuss	All	**ACTION:** a) No action
7. Confirm Next Call	a) Next call: February 18, 2021 (1:30 – 2:30 EDT)	Amanda Shaw	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, February 18, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (PHO):** [redacted] **PE:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **IMPACT:** Karina Top, **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Tracy Freeland, Karin Johnson, Catherine E. Dickson, Carmen Salinas, Sarah Spruin, Christina Jensen, Emily Wahl, [redacted] Joseline Zafack, Ashley Weeks, Jocelyn Bougie, Andrew Atabe, Kaitlin Patterson, Shikha Saxena, Joseline Zafack, [redacted] (CANVASS), Paul Litowitz (Presenter - Health Canada)

Regrets:
NL: [redacted] **ON: (MOH)** [redacted] **QC:** [redacted] **BRDD:** Robert Pless, **CSC:** Samar Sarkesh, **FNIHB:** Kim Daly, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   - i) **Introduction, roll call, agenda, minutes from last meeting**
     - Agenda item 5 from the February 11, 2021 meeting (Delayed onset of vaccination site reaction and lymphadenopathy) has been moved to today's VVWG meeting under agenda item 5 (Reporting Criteria for CAEFISS and Canada Vigilance).
   - ii) **Presentation: Vaccine Surveillance Reference Group/Covid-19 Immunity Task Force**
     - A copy of [redacted] presentation was circulated to the VVWG members after the meeting.
   - iii) **Weekly COVID AEFI Report**
     - On Friday, February 12, 2021, PHAC posted the Adverse Events Section.
     - PHAC is still looking into clarifying and amending the wording on the last page of the report on deaths.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of February 11, 2021 RoD	a) Agenda was approved. b) RoD was approved with no changes.	[redacted]	**ACTION:** a) No action b) No action
2. Alterations to the Anaphylaxis Brighton Collaboration case definition	a) [redacted] provided an update on the alterations to the anaphylaxis Brighton Collaboration case definition ▪ The main issue, if lip swelling should be considered a dermatologic criteria rather than an upper airway swelling. Currently, this is defined as an upper airway swelling and is classified as a level 1 anaphylaxis but a change is being recommended by Brighton Collaboration to change this to a dermatologic criteria.	[redacted]	**ACTION:** **a)** VVWG will wait for Brighton's Collaboration recommendation if lip swelling should be changed to a dermatologic criteria.
3. Expedited Reporting Update a) Flu b) COVID-19	a) Eugenie provided a brief summary of the influenza counts for week 6. b) Theresa provided a brief summary of the COVID-19 vaccine for week 6.	Eugenie Samson/Theresa Procter	**ACTION:** a) Should next week be the last week for flu expedited reporting? This question is being emailed to the VVWG members later today or early tomorrow. b) No action
4. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the Weekly COVID AEFI Report up to February 12, 2021. No safety signals have been identified.	Ashley Weeks	**ACTION:** a) An article on the link to US publication on anaphylaxis following receipt of mRNA COVID-19 vaccines will be shared with VVWG after the meeting.
5. Reporting Criteria for CAEFISS and Canada Vigilance	a) Helen provided a presentation on the Criteria for reporting Adverse Events Following Immunization to CAEFISS.	Helen Anyoti / Paul Litowitz	**ACTION:** a) PHAC will include the following in the document: with the live

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Agenda Item	Description	Lead	Further Actions or Completed
- Delayed onset of vaccination site reaction and lymphadenopathy following COVID-19 vaccination	b) Paul Litowtiz from Health Canada provided a presentation on the Reporting Adverse Reactions by Market Authorization Holders (MAHs) (Manufacturers) ▪ MAHs must comply with the Food and Drugs Act, the Food and Drug Regulations, and the Natural Health Products Regulations with respect to expedited and annual reporting of adverse reactions (ARs) to marketed health products ▪ Mandatory reporting for hospitals ▪ Serious adverse events that are reported to the provinces do not need to be reported to Health Canada ▪ Only one form needs to be filled out for reporting (CAEFISS or Canada Vigilance)		vaccines, we need to take into account the incubation period of the vaccines. b) No action
6. CAEFISS Reporting vs Expedited Reporting	a) This agenda item was not discussed at today's meeting.	Karin Johnson	**ACTION:** a) Karin is sending out a follow-up email to VVWG regarding this agenda item either later today or tomorrow morning.
7. Roundtable	a) No roundtable items were discussed at today's meeting.	All	**ACTION:** a) No action
8. Confirm Next Call	a) Next call: February 25, 2021 (1:30 – 2:30 EDT)	[redacted]	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, February 25, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted]
NU: [redacted] **ON: (PHO):** [redacted] **PE:** [redacted] **SK** [redacted]
[redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **IMPACT:** Karina Top, **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Tracy Freeland, Catherine E. Dickson, Carmen Salinas, Sarah Spruin [redacted] Joseline Zafack, Ashley Weeks, Jocelyn Bougie, Andrew Atabe, Kaitlin Patterson, Shikha Saxena, Joseline Zafack, Helen Anyoti, Saundra Houle, Allison Yeung, Olesia Bissett, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts

Regrets:
NL: [redacted] **ON: (MOH)** [redacted] **QC:** [redacted] **BRDD:** Robert Pless, **CANVASS:** [redacted] **CSC:** Samar Sarkesh, **FNIHB:** Kim Daly

ACTION ITEMS

1. **Action Item Updates**
   i) **Weekly COVID AEFI Report**
   - An article on the link to US publication on anaphylaxis following receipt of mRNA COVID-19 vaccines was shared with VVWG after the meeting.
   ii) **CAEFISS Reporting vs Expedited Reporting**
   - Karin Johnson sent out an email to VVWG to ask if expedited reporting should be stopped as jurisdictions are now reporting to CAEFISS on a weekly basis. Expedited reporting seems to be redundant – the same data is being submitted twice. Responses were received from most jurisdictions and from those who responded they all agreed to halt the expedited reporting.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting - Meeting length - Halting expedited reporting a) Review and approval of agenda b) Review of February 18, 2021 RoD	a) Agenda was approved. b) RoD was reviewed. Amendments can be provided to Carmen Salinas by end of day on February 26, 2021.	Amanda Shaw	**ACTION:** a) Members agreed that VVWG meetings would be extended to 1.5 hours long starting on March 4, 2021. b) Members agreed to halt the expedited reporting for both flu and COVID now that CAEFISS reports are being uploaded weekly. Today was the last day of expedited reporting. Members can provide changes or updates to the RoD to Carmen Salinas by end of day on February 26, 2021 to approve and finalize the RoD from February 18, 2021.
Expedited Reporting Update a) Flu b) COVID-19 c) CANVAS	a) Eugenie provided a brief summary of the influenza counts for week 7. b) Theresa provided a brief summary of the COVID-19 vaccine for week 7. c) [redacted] was unable to attend the meeting. An update may be provided at next week's meeting.	Eugenie Samson/Theresa Procter[redacted]	**ACTION:** **a)** No action **b)** No action **c)** A CANVAS update may be provided at next week's VVWG meeting.
3. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the Weekly COVID AEFI Report up to February 19, 2021. No safety signals have been identified.	Ashley Weeks	**ACTION:** a) PHAC will look into what types of non-serious events are higher for Moderna than Pfizer since the difference is quite striking. The

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Agenda Item	Description	Lead	Further Actions or Completed
			age group will be investigated as well.
4. Delayed onset of vaccination site reaction and lymphadenopathy following COVID-19 vaccination	a) Nooshin provided a presentation on Vaccination site reactions following COVID-19 vaccines CAEFISS (up to February 23, 2021) • [redacted] inquired if there is a difference in age distribution between Moderna and Pfizer. • Delayed onset appears to be occurring in the older age groups. Was this observed in the clinical trial data? • ON inquired if any jurisdictions have changed their guidance or temporal criteria for reporting local reactions to better capture delayed onset reactions.	Nooshin Ahmadipour / Sarah Spruin	**ACTION:** a) A copy of Nooshin's presentation will be sent out to VVWG on February 26, 2021. • PHAC will look into the difference in age distribution between Moderna and Pfizer • Delayed onset appears to be occurring in the older age groups. PHAC will follow-up with HC to see if delayed onset in the older age group was observed in the clinical trial data. • PHAC will be recommending that temporal capture for these AEFIs be extended with the COVID vaccines (this will be added to the COVID specific annex)
5. Roundtable - COVID-19 AESIs	a) ON asked to discuss how the PTs and PHAC are handling COVID-AESIs. What are PTs doing regarding AESIs? Are people collecting the vaccine associated enhanced disease and how it is being defined? • [redacted] noted that the vaccine associated enhanced disease case definition is about to be published. The version of what was	All	**ACTION:** a) PHAC will be presenting the draft revised COVID specific AEFI form and COVID specific annex at next week's VVWG meeting. Definition information will be included. The group will be asked to comment and review. (ON has a similar form and case definition guide).

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Agenda Item	Description	Lead	Further Actions or Completed
	submitted to vaccine for publication is available and has been shared. This has been posted on the CNPHI website. • [redacted] is working on developing a companion guide • It is important to establish whether there was a history of prior COVID or not at the time of immunization. • It is also important if there is serology to document that they were zero negative of COVID at the time they were first immunized which give a different sub group within the case definition • It was noted that you can have vaccine associated enhanced disease and not a vaccine failure if not fully immunized but you can have enhanced disease b) SK inquired if any PTs that have made changes to what they are doing regarding AEFIs regarding COVID? For example, only reportable AEFIs are being submitted. Amanda noted that PHAC has been thinking about developing some kind of educational tools or documents to go along with the COVID specific form and annex. PHAC will need to work with VVWG on developing this. c) Nooshin noted that earlier this morning, some PTs received a follow up note request of the details of the report that they received. The follow-ups are in in two different areas: additional information cases required for secondary medical case review and the second follow up is where there has been a discrepancy		

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Agenda Item	Description	Lead	Further Actions or Completed
	between the Brighton Collaboration level assigned between what the PT submitted versus PHAC medical case review. • If PTs have any additional information that was not included in the report or if PTs can explain how they arrived at the level of certainty that has been indicated in the report that would help finalize this classification in CAEFISS and the changes can be made in a more in depth analysis of CAEFISS.		
6. Confirm Next Call	a) Next call: March 4, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) Next week's meeting has been extended to 1.5 hours long – 1:30pm EDT – 3:00pm EDT.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, January 14, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
BC: [redacted] **AB:** [redacted] (Provincial/Territorial Co-Chair), **MB:** [redacted] **NL:** [redacted] **NS:** [redacted] **NT:** [redacted]
NU: [redacted] **ON (MOH):** [redacted] **ON (PHO):** [redacted] **QC:** [redacted] **SK:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **FNIHB:** Kim Daly, **IMPACT** [redacted] **MHPD:** Shiva Ghimire, Battouli Said, Jhona Rose, Deborah Danoff, **RCMP:** Natalie Toupin

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Saundra Houle, Ashley Weeks, Eugenie Samson, Theresa Procter, Andrew Atabe, Carmen Salinas, Sara Spruin, Jean Nkanza, Jennifer Pennock, Catherine Dickson, [redacted] Kimberley Hutchings, [redacted] (CANVASS)

Regrets:
NB: [redacted] **PE:** [redacted] **YT:** [redacted]

ACTION ITEMS

1. **Action Item Updates**
   i) No action item updates to report.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda	a) Agenda was approved: One agenda item was added – Death in BC temporarily associated with COVID Vaccine.	Amanda	

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Agenda Item	Description	Lead	Further Actions or Completed
b) Review of December 17, 2020 RoD	b) RoD was approved. No changes were made.		
2. Death in BC temporarily associated with COVID Vaccine.	a) BC provided a summary of the AEFI they reported on the death associated with the COVID-19 vaccine. The death of the [redacted] male was ruled as a cardiac arrest by his family physician and the death was not related to the Moderna COVID-19 vaccine. • A discussion needs to take place on how to handle these types of events (vaccines associated with death) given that many of the immunizations that will be given will be in an elderly population where we will potentially be having these coincidental events occurring. • PHAC will be starting with CAEFISS, Canada Vigilance to try to clarify what the criteria is going to be, and which cases should be submitted/reported to CAEFISS and Canada Vigilance. PHAC will work out some clarification and bring it back to VVWG within the next few days. b) [redacted] recommended that having the background rates of the expected mortality by age band for Canada would be very important to have.		**ACTION:** a) [redacted] BC) will be raising the issue of these types of coincidental events (vaccines associated with death) at the SAC meeting today (Jan. 14, 2021). They will need to determine and to provide clarity on how these events will be handled and to determine an approach on how to report these across the country. A consistent approach is required. PHAC will be starting with CAEFISS and Canada Vigilance to try to clarify what the criteria are going to be and which cases should be submitted/reported to CAEFISS and Canada Vigilance. PHAC will work out some clarification and bring it back to VVWG within the next few days.
3. 2020-2021 Influenza Season Update **a) CANVAS** **b) PHAC** **c) COVID-19**	a) CANVASS had nothing to report this week. A final report will be coming in the next week or two. b) Eugenie provided a brief summary of the influenza counts for week 1.	[redacted] Eugenie/ Theresa	**ACTION:** a) No action b) A report will be circulated to VVWG on the percent of AEFIs

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Agenda Item	Description	Lead	Further Actions or Completed
	• After last week's expedited report, some Senior Management had questions on the percent of AEFIs from FluLaval Tetra. An investigative analysis was done at PHAC looking at counts by doses distributed. This will be circulated to VVWG once completed. c) Theresa provided a brief summary of the COVID-19 vaccine for week 1. • A COVID assessment has not been done yet. Only an assessment has been done for the flu. An assessment process for COVID is now being worked on. • PHAC is setting up a working group looking at Background rates.		from FluLaval Tetra once completed. c) No action
4. Brighton Collaboration Level of Diagnostic Certainty	a) We have to ensure that reports are consistently coded by the reporting FPT and in CAEFISS in terms of seriousness and assessment for BC diagnostic certainty. We need to find the most efficient approach for these. b) Amanda noted that a CNPHI alert for every death might not be useful. The Vaccine Safety team will really need to clarify when we expect a CNPHI and when not to so we can have consistency across the country.	Nooshin	**ACTION:** a) A survey will be sent out after the call today regarding what type of assessment is done on each AEFI before it is sent for expedited and full AEFI case.
5. Schedule for Regular Reporting	a) Amanda noted that VVWG members have not all responded to an email sent out in regards to COVID-19 vaccine AEFI reporting. Members need to provide a response if they plan to report on the weekends or not. If jurisdictions will be reporting on the weekend, PHAC-VS Team will need to arrange for staff to be available to receive these reports. Members have been asked to send their	Amanda	**ACTION:** a) Members have been asked to send their responses in to the VVWG email account as soon as possible if they plan on reporting on the weekends or not on the COVID-19 Vaccine AEFI reports;

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Agenda Item	Description	Lead	Further Actions or Completed
	responses in to the VVWG email account as soon as possible.		
6. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the weekly COVID AEFI report. • It was noted that the cutoff date to submit the reports are Fridays by 4pm. • It was pointed out that the data on the doses administered is a day removed. This will now be indicated on the report.	Ashley Weeks	**ACTION:** a) The data on the doses administered is a day removed. Moving forward, this will be noted on the report.
7. Organization of the Vaccine Safety (VS) Team	a) A VS Team org chart was provided to VVWG before the meeting. It shows the roles of each team member. Any questions can be sent to the VVWG email inbox.	Amanda	**ACTION:** a) Questions regarding the roles of the Vaccine Safety Team can be sent to the VVWG email inbox.
8. Roundtable	a) No items were presented at the roundtable.	All	**ACTION:** a) No action.
9. Confirm Next Call	a) Next call: January 21, 2021 **Please Note:** All VVWG teleconference will be held on a weekly basis for one hour long and there will be no difference between monthly calls and Flu/COVID calls.	Amanda	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, January 21, 2021 from 1:30 – 2:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
BC: [redacted] **AB:** [redacted] (Provincial/Territorial Co-Chair), **MB:** [redacted] **NT:** [redacted] **ON (MOH):** [redacted]
[redacted] **ON (PHO):** [redacted] **QC:** [redacted] **SK:** [redacted]
[redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **FNIHB:** Kim Daly, **IMPACT:** [redacted] **MHPD:** Shiva Ghimire, Battouli Said, Jhona Rose, Deborah Danoff

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Ashley Weeks, Eugenie Samson, Theresa Procter, Helen Anyoti, Catherine E. Dickson, Tracy Freeland, Allison Yeung, Andrew Atabe, Carmen Salinas, Sara Spruin, Jean Nkanza, Emily Wahl, Erica Tice, [redacted] Kimberley Hutchings [redacted] (CANVASS), Joseline Zafack

Regrets:
NB: [redacted] **NL:** [redacted] **NU:** [redacted] **PE:** [redacted] **YT:** [redacted] **RCMP:** Natalie Toupin

ACTION ITEMS

1. **Action Item Updates**
   - i) **Death in BC temporarily associated with COVID Vaccine (Status update)**
     - The death case has been deemed a cardiac arrest by the coroner and it is not COVID related therefore, this death will not be reported.
   - ii) **2020-2021 Influenza Season Update**
     - A report was circulated to VVWG on the percent of AEFIs from FluLaval Tetra.
   - iii) **Brighton Collaboration Level Diagnostic Certainty**
     - A survey was sent out to VVWG after the teleconference call on January 14, 2021 regarding what type of assessment is done on each AEFI before it is sent for expedited and full AEFI case.
   - iv) **Schedule for Regular Reporting**

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- VVWG members were asked to send in their responses as soon as possible if they plan on reporting on the weekends or not on the COVID-19 Vaccine AEFI reports. Most jurisdictions have provided their response.

v) Weekly COVID AEFI Report

- The Weekly COVID AEFI Report now indicates that the data on the doses administered is a day removed.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of January 14, 2021 RoD	a) Agenda was approved. b) RoD was approved. No changes were made.	[redacted]	
2. 2020-2021 Influenza Season Update a) PHAC b) COVID-19	a) Eugenie provided a brief summary of the influenza counts for week 2. ▪ The following questions were asked: Any increase in seizures? Do we have a specific age group or vaccine for the seizure case? Do we have a specific age group for CAEFISS? - Karin will do a quick analysis of all the seizure cases that have been reported and provide a response to VVWG next week b) Theresa provided a brief summary of the COVID-19 vaccine for week 2. ▪ [redacted] asked if it is possible to report on the National Summary the number of allergic reactions. - Karin noted that this could be added and BC concurred. The category can be broken down by anaphylaxis versus non-anaphylaxis allergic events.	Eugenie/Theresa	**ACTION:** a) Karin will do a quick analysis of all the seizure cases that have been reported and provide a response to VVWG next week. b) Karin will add to the National Summary the number of allergic reactions. The category will be broken down by anaphylaxis versus non-anaphylaxis allergic events.
3. Analytics a) Summary of FluLaval Tetra Investigation	a) NB asked if the FluLaval Tetra lot had been released or not. - MB has not released the FluLaval Tetra lot.	Kimberley Hutchings	**ACTION:** a) Jurisdictions who did not provide a response can email Carmen to advise if they released or not the

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Agenda Item	Description	Lead	Further Actions or Completed
b) Background Rates Working Group	- QC has used all of the FluLaval Tetra lot in question (KX9F7). - ON released the FluLaval Tetra doses that were in quarantine in November 2020. These were released back into the system for administration. b) Kimberly Hutchings provided a summary of the Background Rates Working Group ▪ PHAC is working on calculating background rates for the AESIs for COVID. ▪ PHAC will calculate background rates for the general population using DAD data. ▪ A small Background Rate Working Group was created and the first meeting was held on January 20, 2021. The WG will develop a national methodology (case definitions and algorithms). This will enable PTs the ability to compare their provincial/territorial rates with the national rate. ▪ A draft will be shared with VVWG for review/comments/input once completed.		FluLaval Tetra lot in question (KX9F7). b) A draft will be shared with VVWG for review/comments/input once completed.
4. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the weekly COVID AEFI report up to January 16, 2021. ▪ Ashley noted that there was one reported death to Canada Vigilance during this time period. PHAC is under discussions on how to best report these types of deaths. ▪ One jurisdiction asked, will the death information be available on-line. PHAC responded, that it should be available next week (all personal information will be removed before being publically available).	Ashley Weeks	**ACTION:** a) The two reporting systems will need to be discussed further with Senior Management. This will be re-visited at the next VVWG meeting on January 28, 2021.

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ Questions were asked by the Working group regarding CAEFISS vs. Canada Vigilance. - Vigilance Canada information is not entered into CAEFISS; these are two separate databases - A member inquired about how are duplicates identified. Currently, a working group reviews all the reports and tries to identify duplicates based on the information that is available (Vigilance Canada does not have data such as; the date of birth, name etc. but they do have the age, sex and time to onset). - This may not be manageable as the number of reports increases. At this time, PHAC is looking into an automated process - Each system has it's own reporting criteria – this should be outlined for the online reporting		
5. CAEFISS Criteria for COVID AEFIS Death's following COVID vaccine	a) Amanda noted that CAEFISS is reviewing their reporting criteria for AEFI deaths. ▪ An appendix will be added to the users guide ▪ Currently, the definition is: "any AEFI with a temporal association with vaccine and no other clear cause." ▪ [redacted] indicated that allergic reactions and anaphylaxis category be added to the appendix ▪ PHAC is currently working on this and a draft will be presented to VVWG at the next meeting on January 28, 2021.	Amanda	**ACTION:** a) PHAC will present a draft to VVWG at the next call on January 28, 2021.

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ A follow-up presentation to CIC will take place on February 4, 2021.		
6. Roundtable	a) BC asked Health Canada what operators they should be using when searching the Canada Vigilance adverse reaction on-line database for these vaccines. ▪ Health Canada noted that there was a delay with the coding and it was not posted on the website. The new target date to start this is Friday, January 22, 2021. HC will share the keyword search with VVWG once they receive the coding from Canada Vigilance. b [redacted] indicated that the new Brighton case definitions have been formally accepted by Vaccine and will be published in the near future (date unknown at this time). The accepted versions will be posted on the Brighton website.	All	**ACTION:** a) Health Canada will share the keyword search with VVWG once they receive the coding from Canada Vigilance. b) [redacted] will advise VVWG when the new Brighton case definitions will be published.
7. Confirm Next Call	a) Next call: January 28, 2021 (1:30 – 2:30 EDT)	[redacted]	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, January 28, 2021 from 2:00 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair), **MB:** [redacted] **NB:** [redacted] **NL:** [redacted]
[redacted] **NS:** [redacted] **NT** [redacted] **ON (MOH):** [redacted] **ON (PHO):** [redacted] **PE:** [redacted]
[redacted] **QC:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **FNIHB:** Kim Daly, **IMPACT** [redacted] **MHPD:** Shiva Ghimire, Jhona Rose, Deborah Danoff, Kathleen Eng **RCMP:** Natalie Toupin

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Nooshin Ahmadipour, Helen Anyoti, Ashley Weeks, Eugenie Samson, Theresa Procter, Helen Anyoti, Catherine E. Dickson, Tracy Freeland, Allison Yeung, Carmen Salinas, Sara Spruin, Jean Nkanza, Emily Wahl, Erica Tice, [redacted] (CANVASS), Joseline Zafack, Alexander Szumillas, Jasminka Draca,

Regrets:
BC: [redacted] **NU:** [redacted]

ACTION ITEMS

1. **Action Item Updates**
   - **i) 2020-2021 Influenza Season Update**
     - **Flu Report:** Karin sent out the analysis of all the seizure cases to VVWG the week of January 25, 2021.
     - **COVID-19:** Karin added the number of allergic reactions to the National Summary and it has been broken down by anaphylaxis versus non-anaphylaxis allergic events.
   - **ii) Analytics**
     - No further responses have been received from jurisdictions on whether or not they have released the FluLaval Tetra lot in question (KX9F7).
     - The Background Rate Working Group is still working on drafting a National Methodology. It will be shared with VVWG for review/comments/input once completed.
   - **iii) Weekly COVID AEFI Report**
     - The two reporting systems were discussed by Senior Management the week of January 25, 2021.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of January 21, 2021 RoD	a) Agenda was approved. b) The draft RoD was circulated to the members. Additional comments and/or changes can be sent to Carmen via email.	Amanda Shaw	**ACTION:** a) No action b) Comments and/or changes to the RoD from January 21, 2021 can be sent to Carmen via email to the VVWG inbox.
2. Expedited Reporting Update a) Flu b) COVID-19	a) Eugenie provided a brief summary of the influenza counts for week 3. b) Theresa provided a brief summary of the COVID-19 vaccine for week 3.	Eugenie Samson/Theresa Procter	**ACTION:** a) No action b) At the next VVWG meeting or at the one following, PHAC will go through what our inclusion criteria is for COVID, the user guide and the annex for COVID.
3. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the weekly COVID AEFI report up to January 23, 2021.	Ashley Weeks	**ACTION:** a) The Weekly COVID AEFI Report will go live tomorrow afternoon (January 29, 2021). The link will be sent out to VVWG on January 29, 2021.
4. Deaths following COVID-19 vaccine	a) Catherine provided a presentation on the "Submission of reports of death following receipt of COVID-19 vaccine to PHAC". - The Vaccine Safety Team is recommending that P/Ts notify PHAC and report all deaths that occur within 30 days of vaccination regardless of cause.	Catherine E. Dickson	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	- PHAC and Health Canada will work together to consolidate reports as much as possible to avoid duplicate counts. - PHAC is exploring the idea of having an info graphic or a one to two pager on the PHAC website to explore the background death rates so that there is some context when people see it reported on the weekly report		
5. Roundtable	a) No additional items, comments or questions.	All	**ACTION:** a) No action
6. Confirm Next Call	a) Next call: February 4, 2021 (1:30 – 2:30 EDT)	Amanda Shaw	**ACTION:** a) No action.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, March 4, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
BC: [redacted] **NB:** [redacted] **NS** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted]
(PHO): [redacted] **PE:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne, **IMPACT** [redacted] **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Nooshin Ahmadipour, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Tracy Freeland, Carmen Salinas, Sarah Spruin, [redacted] Joseline Zafack, Ashley Weeks, Jocelyn Bougie, Kaitlin Patterson, Shikha Saxena, Helen Anyoti, Saundra Houle, Allison Yeung, Olesia Bissett, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts

Regrets:
AB [redacted] (Provincial/Territorial Co-Chair, **MB:** [redacted] **NL:** [redacted] **QC:** [redacted] **CANVAS:** [redacted]
CSC: Samar Sarkesh, **FNIHB:** Kim Daly, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   - i) **Introduction, roll call, agenda, minutes from last meeting**
     - No amendments for the February 18, 2021 RoD were received from members. The RoD is considered approved and has been posted to CNPHI.
     - Meetings will now be 1.5 hours long starting on March 4, 2021.
   - ii) **Expedited Reporting Update**
     - Members agreed to halt the expedited reporting for both flu and COVID now that CAEFISS reports are being uploaded weekly. February 25, 2021 was the last day of expedited reporting.
   - iii) **Delayed onset of vaccination site reaction and lymphadenopathy following COVID-19 vaccination**
     - Nooshin provided VVWG members a copy of her presentation on February 26, 2021.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting - Announcement of new Interim Director a) Review and approval of agenda b) Review of February 25, 2021 RoD	a) Agenda was approved with no additional items added. - Susanna Ogunnaike-Cooke was introduced as the new Interim Director to cover for Jennifer Pennock [redacted] - b) RoD was reviewed. Amendments can be provided to Carmen Salinas by end of day on March 5, 2021.	Amanda Shaw	**ACTION:** a) Expedited reporting has been halted but if there are any other suggestions or information for other analysis, this can be provided to PHAC via the VVWG email inbox. b) Members can provide changes or updates to the RoD to Carmen Salinas by end of day on March 5, 2021 to approve and finalize the RoD from February 25, 2021.
2. Weekly COVID AEFI Report	a) Ashley provided a brief summary of the content changes to the Weekly COVID AEFI Report which will be implemented on March 5, 2021 • An Introductory text is being implemented to include more background and context • A summary tab is being added based on feedback in addition to the technical report tab • A technical note is being added on how anaphylaxis is being determined based on the Brighton Collaboration and levels.	Ashley Weeks	**ACTION:** a) No action
3. CAEFISS Weekly Report	a) Karin provided a brief summary of the CAEFISS Weekly Report. • NB inquired as to why is the date report received being used rather than the date administered for AEFIs over time. Karin noted that PHAC uses the date the report is received. NB uses the date the AEFI is reported to public health.	Karin Johnson	**ACTION:** a) PHAC will look into the AEFI reported to public health to see how different it is compared to what is currently being used. b) PHAC will pull data on COVID toes. Nooshin will also confirm with the

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Agenda Item	Description	Lead	Further Actions or Completed
	• [redacted] inquired if anyone has seen reports on COVID toes (red swollen toes) after receiving the vaccine. There have been reports in the US and in Europe. [redacted] noted that they are try to decide if they should move forward with a Brighton Case Definition		CAEFISS team if there are any reports in the CAEFISS system. c) PHAC will share at the next VVWG meeting, March 11, 2021, web analytics regarding the weekly report.
4. COVID AEFI Form and Annex	a) Karen presented the revisions to the AEFI form and user guide. • The National form is comprehensive and only minimal changes are required • There are limitations regarding data that is submitted to PHAC and this issue needs to be addressed • Elements that have been added are: o Indigenous status o Lactating women o Setting of immunization (i.e. Long Term Care Homes vs. community) o Diluent information required in addition to expiry date (WHO recommendation) o More check boxes added including more details for current tick boxes o COVID AESIs added (based on Brighton Collaboration recommendation) o Specific guidance added to the form to ensure data quality and detail of reported information - Past COVID-19 infection information requested - Specific immunization errors have been added - Inappropriate vaccine schedule tick box	Karen C. Roberts	**ACTION:** a) Carmen Salinas will send out the COVID AEFI form and annex to the VVWG members after the meeting to ask for input and/or suggestions by Wednesday, March 10, 2021. Input / Suggestions can be sent to Karen C. Roberts or to the VVWG email inbox.

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Agenda Item	Description	Lead	Further Actions or Completed
	• User guide: Some AESI definitions are still under development ○ COVID-19 specific annex is not necessary as the majority of the changes and additions made in the form and in the user guide will be useful for all vaccine AEFI reporting.		
5. Background Rates Update	a) Sarah provided an update on the Background rates. • Key methodology has been finalized for anaphylaxis and Bell's Palsy • Included the background rates found in the literature in conjunction with what PHAC calculated • ACCESS (in Europe) has published some background rates but only for anaphylaxis • Anaphylaxis has three definitions • Bell's Palsy has one definition • The next conditions that the Working Group plan to review are: GBS, arrhythmias, transverse myelitis, and ADEM. Suggestions for any other AEFIs from the WG are welcomed. • [redacted] inquired if the rates will be broken down by age especially for Bell's palsy. Some of these results are available however, just clearing results for small cell sizes, etc. [redacted] - **Update:** • [redacted] provided an update to advise that they are preparing companion guides to various Brighton case definitions. They are currently being finalized and they should be posted on Friday, March 5, 2021. This will cover Bell's palsy, anaphylaxis, GBS, etc.	Kimberley Hutchings /Sarah Spruin	**ACTION:** a) It was noted that the background rates should use the same denominator (i.e. per 100,000) which PHAC will work on. b) The background rates will be shared on CNPHI. PHAC will look into posting these rates with the Canadian Immunization Guide (CIG) at a later date.

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Agenda Item	Description	Lead	Further Actions or Completed
	• A systematic review was conducted on background rates by country, age, sex, etc., if available. • The Brighton Collaboration is also working on a website to share this information. • [redacted] will send this to Nooshin to post on CNPHI.		
6. Roundtable	a) No items were discussed at the Roundtable.	ALL	**ACTION:** a) No action
7. Confirm Next Call	a) Next call: March 11, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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"Rehearsal Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, March 11, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] Provincial/Territorial Co-Chair, **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted]
[redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne, **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Tracy Freeland, Carmen Salinas, Sarah Spruin, [redacted] Ashley Weeks, Jocelyn Bougie, Kaitlin Patterson, Shikha Saxena, Helen Anyoti, Saundra Houle, Allison Yeung, Olesia Bissett, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts, **CANVAS:** [redacted]

Regrets:
NL: [redacted] **NT:** [redacted] **NU:** [redacted] **PE:** [redacted] **QC** [redacted] **CSC:** Samar Sarkesh, **FNIHB:** Kim Daly, **IMPACT:** [redacted] **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   - i) **Introduction, roll call, agenda, minutes from last meeting**
     - No amendments for the February 25, 2021 RoD were received from members. The RoD is considered approved and has been posted to CNPHI.
   - ii) **CAEFISS Weekly Report**
     - PHAC provided web analytics regarding the weekly report
   - iii) **COVID AEFI Form and Annex**
     - An email was sent out to the VVWG members to provide their input and or suggestions on the COVID AEFII form and Annex.
   - iv) **Background Rates Update**
     - PHAC is working on the background rates to use the same denominator.
     - Background rates have been shared on CNPHI

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of March 4, 2021 RoD	a) The agenda was modified to accommodate VVWG members to attend the **PHAC: COVID-19 Vaccines Webinar - Delayed Injection Site Reactions** . - Agenda item 3, "**CAEFISS Weekly Report**" will be moved to next week's agenda. - Agenda item 6, Roundtable on "**Capacity of each jurisdiction to process and report AEFIs as the campaign expands**" will be moved to next week's agenda. - Agenda item 6, Roundtable, "AstraZeneca LOT on hold in EU" will be discussed briefly as agenda item 2. b) RoD was reviewed. Amendments can be provided to Carmen Salinas by end of day on March 12, 2021.	[redacted]	**ACTION:** a) - Agenda item 3, "**CAEFISS Weekly Report**" will be moved to next week's agenda. - Agenda item 6, Roundtable on "**Capacity of each jurisdiction to process and report AEFIs as the campaign expands**" will be moved to next week's agenda. b) Members can provide changes or updates to the RoD to Carmen Salinas by end of day on March 12, 2021 to approve and finalize the RoD from March 4, 2021.
2. Roundtable - AstraZeneca LOT on hold in EU	a) Robert Pless from Health Canada - BRDD provided an update on the AstraZeneca LOT on the quality side. ▪ In the Pre-licensure submission, there was no issue with thromboembolic events and it was not considered a concern by the EMA either in their assessment. ▪ Janssen did have it as a potential AEFI ▪ Thromboembolic events were on the list of potential safety issues. There was an imbalance of the number of cases in the clinical trial between the vaccine group and the placebo group of 15 to 10. ▪ COVAX supply for Canada will not be coming from Europe (not made in Europe) and Health Canada will be closely monitoring the situation		**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ BC inquired if there is any information from the Covishield vaccine (the one produced in India). Robert noted that it is not coming from Europe but from India. The submission was based on the AstraZeneca clinical submission with a limited number of subjects who received the Covishield vaccine in an immunogenicity analysis. That issue has not come up with Covishield. ▪ 500,000 doses of Covishield are being distributed this week in Canada.		
3. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. ▪ There was no new content or information from last week. ▪ YK inquired if PHAC knows if local reactions are associated with technique of vaccine administration (landmarking, proper technique, etc.) PHAC will look further into this and report to VVWG next week. ▪ MB inquired if PHAC has information regarding immunization error in CAEFISS and vaccine site reactions. It was noted that this might not be categorized as an error but as an incorrect technique is not an error. More education to the immunizers was suggested to be provided.	Ashley Weeks	**ACTION:** a) PHAC will look into local reactions associated with technique of vaccine administration and report back to VVWG next week.
4. CAEFISS Weekly Report	a) The CAEFISS Weekly Report was moved to next week's agenda.	Karin Johnson	**ACTION:** a) This will be moved to next week's agenda.
5. CANVAS Update	a) [redacted] provided a presentation on CANVAS.	[redacted]	**ACTION:** a) Questions on today's presentation can be sent to the VVWG email

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Agenda Item	Description	Lead	Further Actions or Completed
			inbox and can be answered at next week's meeting.
6. Rehearsal of Concept	a) Susanna Ogunnaike-Cooke was unable to present today. Susanna will provide an update at next week's meeting. Amanda provided a brief update. ▪ Preparation at the jurisdictional level for the main roll-out of the COVID vaccines. ▪ PHAC is meeting with each provincial/territorial partner if they are ready. ▪ PHAC would like to know how everyone is feeling about being ready to collect and report the AEFIs, which are going to increase significantly in the next few months. ▪ PHAC would like to know if you need support and what type of support is required. ▪ This will be added to the roundtable at next week's meeting.	Susanna Ogunnaike-Cooke	**ACTION:** a) This will be discussed further at next week's meeting. PHAC is asking that each jurisdiction be prepared with a summary of how things are looking in their province for next week's meeting and if they need support and what type of support is required.
7. Roundtable - Capacity of each jurisdiction to process and report AEFIs as the campaign expands - AstraZeneca LOT on hold in EU	a) This roundtable item is being moved to next week's agenda.	ALL	**ACTION:** a) This will be moved to next week's agenda.
8. Confirm Next Call	a) Next call: March 18, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Friday, March 12, 2021 from 2:30 – 3:30 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial/Territorial Co-Chair, **BC:** [redacted] **MB** [redacted] **NB:** [redacted] **NL:** [redacted] **NS:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **SK:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne, **MHPD:** Shiva Ghimire, Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Eugenie Samson, Theresa Procter, Kimberley Hutchings, Tracy Freeland, Carmen Salinas, Sarah Spruin [redacted] Ashley Weeks, Jocelyn Bougie, Allison Yeung, Karen C. Roberts, Natalie Dayneka, Julie A. Laroche, Kristin Bennet, [redacted] Andrew Atabe, Christina Jensen

Regrets:
NT: [redacted] **PE:** [redacted] **QC:** [redacted] **YT:** [redacted] **CANVAS:** [redacted] **CSC:** Samar Sarkesh, **FNIHB:** Kim Daly, **IMPACT:** [redacted] **RCMP:** Roxanne Tauvette

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction	a) Amanda provided a brief summary of the high cases of anaphylaxis following the Pfizer COVID -19 vaccine. • On March 11, 2021, PHAC received a notification from British Columbia. The notification was about a high number of anaphylaxis events with the Pfizer-BioNTech COVID-19 Vaccine [redacted] British Columbia reached out to PHAC.	Amanda Shaw	**ACTION:** a) No action
2. Summary from BC	a) [redacted] provided a summary of what they have seen in BC [redacted]	[redacted] (BC)	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	• British Columbia (BC) recorded18 AEFI reports for events managed as anaphylaxis [redacted] (Pfizer vaccine). • A total of 45,000 doses [redacted] were shipped to BC on February 17, 2021, for a rate of 40 anaphylaxis events per 100,000 doses distributed in BC (or 33% of all anaphylaxis events in BC with the Pfizer-BioNTech COVID-19 Vaccine) • Of the 18 AEFI reports for anaphylaxis events, 10 anaphylaxis events were classified as the Brighton Collaboration level 1, 2 or 3 (or a rate of 22 per 100,000 doses distributed in British Columbia). • [redacted] • There were also 13 other allergic events reported [redacted] that is about 12% of all of BC's allergic events of the Pfizer vaccine in BC. • The reports were received from all Health Regions in BC. There were 15 AEFI reports in females and 3 AEFI reports in males, with age ranging from 23 to 68 years old. Nine of the 18 AEFI reports have reported history of allergic reactions. • Higher rates of anaphylaxis in British Columbia were observed compared to what has been observed nationally for anaphylaxis.		
3. Summary of data in CAEFISS	a) Kim provided a summary of data in CAEFISS • This analysis only includes the cases that met the Brighton Criteria, level 1 to 3. • Other allergic reactions are excluded from this and this only includes cases we have reviewed. There are still 10 cases outstanding. • To date, the overall rate of anaphylaxis is equal between Moderna and Pfizer.	Kim Hutchings	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	• In terms of the lot numbers, when the anaphylaxis cases were broken down, the reports varied. Some lot numbers do not have any reports of anaphylaxis and some do. It is not necessarily the lot that BC has flagged that has the most anaphylaxis cases. • Overall, our rate is 15.1 per million doses distributed • Background rates were updated a couple of weeks ago and additional codes needed to be added therefore, the background rates are much higher now. The rate is now 212 per million which is quite high.		
4. Distribution of LOT across Canada	a) Karin provided a summary of the Lot distribution in Canada. • Nine PTs received [redacted] • 40% of the doses received were in Ontario followed by 22% in British Columbia and about 17% in Quebec. • All other provinces reported few or no anaphylaxis cases with this lot • One PT inquired if this was a new lot and it was noted that this particular lot was shipped on February 15, 2021. • Another PT inquired if BC tends to have a higher rate of anaphylaxis reporting and is this a trend. According to PHAC data, the rate was not, the highest reported in the country but mid range. BC noted that they are the third highest for reporting. This is a higher reporting rate than they would get for the flu season as a comparison. BC usually sees less than one per 100,000 reports. They are seeing higher rates than what they have seen from other vaccines within BC where they can compare out in an adult population. • [redacted]	Karin Johnson	**ACTION:** a) Health Canada will reach out to the manufacturer to find out where else this lot has been distributed to internationally.

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Agenda Item	Description	Lead	Further Actions or Completed
	• [redacted] has been fully distributed and used up in British Columbia		
5. Summary from Canada Vigilance and Health Canada	a) Canada Vigilance and Health Canada provided a brief summary • In a search of the Canada Vigilance Program on March 12, 2021 (up to and including March 11, 2021), seven foreign and no domestic spontaneous reports with the Pfizer-BioNTech COVID-19 Vaccine [redacted] were retrieved. The seven foreign reports were serious and originated from a physician in Panama. One patient was female (unknown gender in 6 patients, unknown age in all patients). All the reports described pruritic rash on the abdomen, back, arms and ears (not on the face) within 30 minutes after vaccination. The patients' medical history and concomitant medications were not reported. The outcome is reported as unknown in all reports. • The MAHs, Pfizer Canada ULC and BioNTech Manufacturing GmbH, did not report adverse reactions [redacted] in the Summary Monthly Safety Reports covering the reporting period of December 1, 2020 to January 31, 2021.	Jhona Rose (Health Canada)	**ACTION:** **a)** Health Canada
6. Roundtable	a) A summary of anaphylaxis events with the Pfizer-BioNTech COVID-19 vaccine lot number E and territories:	ALL	**ACTION:** a) It was recommended that PHAC could start reviewing cases

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Agenda Item	Description	Lead	Further Actions or Completed
	Alberta: [redacted] anaphylaxis and [redacted] allergic reaction **Manitoba:** [redacted] other allergic reactions **Ontario:** [redacted] anaphylaxis **Quebec:** 0 anaphylaxis **New Brunswick:** [redacted] anaphylaxis **Nova Scotia:** 0 anaphylaxis **Newfoundland and Labrador:** no doses received **Prince-Edward-Island:** no representative on the call **Saskatchewan:** [redacted] anaphylaxis **Territories:** no doses received		before a full medical review commences. b) **Next Steps for BC:** A review of the reports will need to be done more closely. More education may need to be provided to immunizers about anaphylaxis and recognizing anaphylaxis. c) PHAC will do a follow up looking more in depth in the CAEFISS database and PHAC will do more investigation and this will be shared with BC. It will then be shared with VVWG at the next meeting on March 18, 2021.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, March 18, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] **BC** [redacted] MB: [redacted] **NB:** [redacted] **NS:** [redacted]
[redacted] **NT:** [redacted] **NU:** [redacted] **ON: (PHO):** [redacted] **PE:**
[redacted] **QC** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Eugenie Samson, Theresa Procter, Tracy Freeland, Carmen Salinas, Sarah Spruin, Ashley Weeks, Jocelyn Bougie, Andrew Atabe, Kaitlin Patterson, Saundra Houle, Allison Yeung, Christina Jensen, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts, [redacted] Erica Tice

Regrets:
CANVAS: [redacted] **FNIHB:** Kim Daly, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) Weekly On-line COVID AEFI Report
- PHAC will report back to VVWG next week about the local reactions associated with technique of vaccine.

ii) CANVAS Update
- There were no questions sent to the VVWG inbox regarding the CANVAS update.

iii) Rehearsal of Concept
- Jurisdictions provided a summary of what strategies, activities, and capacity increases are being planned /used within provinces and territories and if they require support from PHAC and what type of support they may need.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with no additional items. b) RoD was reviewed. Amendments can be	Amanda Shaw	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of March 11, 2021 RoD	provided to Carmen Salinas by end of day on March 19, 2021.		b) Members can provide changes or updates to the RoD to Carmen Salinas by end of day on March 19, 2021 to approve and finalize the RoD from March 11, 2021.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. It will be posted on March 19, 2021. • MB inquired if PHAC could show how the rates compare to other vaccines such as, the reporting rate we are getting for COVID. How that rate compares to other vaccines, and is it more reactogenic than other vaccines in general, maybe other vaccines, specifically flu as one example. • PHAC noted that it could be added into the results shared with VVWG.	Ashley Weeks	**ACTION:** a) PHAC will start including this in our presentation to VVWG.
3. CAEFISS Analysis - Bells Palsy - Anaphylaxis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to March 12, 2021. The results of the analysis of Bells Palsy were also provided • Only one of the 26 Bells Palsy reports was classified as serious. • NB inquired if PHAC is reporting on medically important AEFI and are they included in the serious one. If not, is PHAC planning to report the number of AEFIs that are classified as medically important? - Karin noted that medically important would be included in part of the serious category. Medically important is mainly reported with Health Canada and PHAC does not have any in CAEFISS that are	Karin Johnson	**ACTION:** a) Health Canada will send out the definition of **medically important event** to VVWG and the criteria that is used to classify their AEFIs as medically important events. b) PHAC will send out the definition of **serious medically important** to VVWG. c) The Pfizer [redacted] that was in question from BC last week was not noted on the report. PHAC will look into this and add this to the report next week

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Agenda Item	Description	Lead	Further Actions or Completed
	classified as medically important. They are classified as serious or non-serious based on the severity score. • BC inquired about what are the criteria for the medical reviews and what the criteria would be for Causality Assessment. BC asked what the differences are. - Nooshin noted that they are both the same. All serious events and all of the adverse events of special interest for COVID vaccine undergo causality assessment. - Catherine noted that there are two levels of causality assessment. The first level is the one that the medical reviewers do as part of their medical review. This is done for all the serious cases they review. The second level refers to ongoing plans to develop a Causality Committee and for these it would be specific cases where there is a concern with the medical review (an unusual case). • BC inquired about medically important events. Bells Palsy would not be considered as a serious event however, the one event that was reported as serious was because the person was hospitalized and this is how it met the criteria of important. - Health Canada will provide VVWG with the definition of medically important events and the criteria that is used to classify their AEFIs as medically important events.		

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Agenda Item	Description	Lead	Further Actions or Completed
	b) Kim provided the results of the analysis of anaphylaxis. There have been no changes in trends since the previous update. • All of these have undergone medical review. There are 65 cases or less that are pending review. • A PT inquired, is the medical case review the process by which you do the levelling or do you have an automated system for doing it? - Catherine noted that we do it as part of the Brighton Collaboration levels of certainty we do that as part of our medical case review and have two reviewers check it against each other to ensure there are no errors. • [redacted] from Pfizer in question from last week was not noted in the report. PHAC will look into this for next week's report.		
4. CANVAS Update	a) [redacted] was unable to attend the meeting. The CANVAS update will be moved to next week's meeting.	[redacted]	**ACTION:** a) This will be moved to next week's agenda.
5. AstraZeneca hold in EU - Update on current situation - AEFIs of concern	a) Jhona Rose provided a summary of the AstraZeneca hold in EU. • The EU held a press conference today and revealed that the benefits of the AstraZeneca COVID-19 vaccine continue to outweigh the risks for use. • Health Canada will issue a similar statement as the EU press conference to say that the benefits of AstraZeneca COVID-19 vaccine continue to outweigh the risks for use in Canada and encourages Canadians to get immunized with any of the recommended COVID-19 vaccines that are authorized in Canada.	Jhona Rose (HC) / Catherine Dickson (PHAC)	**ACTION:** a) Health Canada will provide a list of other countries that have been approved to use COVISHIELD and will summarize and provide to VVWG.

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Agenda Item	Description	Lead	Further Actions or Completed
	b) Catherine provided a summary of AEFIs of concern. • The events of concern that were reported out of Europe were not just from a thrombotic event where there is a blood clot that is detected. This tended to present as blood clots with thrombocytopenia as well as frequently bleeding. These were somewhat unusual and often quite severe events that they were reporting. PHAC has been monitoring the reports that have been coming in through CAEFISS. PHAC currently does not have anything from COVIDSHIELD reported yet through CAEFISS. Canada Vigilance has received a small number at this time. • PHAC has done a review and to date the following reports have been made: 6 strokes (4 - Pfizer, 1 - Moderna, 1 - COVISHIELD), 2 Pulmonary embolism (2 - Pfizer). To date, nothing has been reported on embolism or other factors such as, bleeding, strokes and pulmonary embolism, thrombocytopenia. At this time, there is nothing to be concerned about at this time but PHAC will continue to monitor this. • ON inquired if the product monographs will be changed to make reference to specific counselling about the risk of these events especially for people under 50 looking at the way the EMA position was worded and making note of observed events being greater than expected in that population under 50. - Health Canada noted it will be changed but they are waiting for details on what		

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Agenda Item	Description	Lead	Further Actions or Completed
	[redacted] • BC inquired what their understanding might be around the biological mechanisms for a causal association. - HC noted that there is a discussion that is taking place about potential changes to the coagulation pathway but there is no data available at this point. The EMA presented a number of theoretical biological mechanisms but nothing that had any data.		
6. Advisory Committee on Causality Assessment (ACCA) re-establishment	a) Susanna introduced Dr. Natalie Dayneka who is new to the VSS team and will be working on re-establishing the Advisory Committee on Causality Assessment (ACCA). • Natalie will be working on the causality assessment. She will be contacting jurisdictions to discuss this matter further.	Susanna Ogunnaike-Cooke / Natalie Dayneka	**ACTION:** a) No action
7. Rehearsal of Concept	a) Susanna Ogunnaike-Cooke provided a brief summary of the Rehearsal of Concept. • There was a Rehearsal of Concept that was conducted fairly recently that was to stage how we were all going to be prepared for phase 2, which is the significant increase in the availability of vaccines in Canada to be rolled out (anticipated high increase in AEFI reports).	Susanna Ogunnaike-Cooke	**ACTION:** a) No action
8. Roundtable - Expected increase in AEFI reporting with phase 2 vaccine roll-out: What strategies, activities and capacity increases are being planned/used within P/Ts?	a) Jurisdictions were asked to provide a summary of what strategies, activities, and capacity increases are being planned /used within provinces and territories. Also, is there some support needed that PHAC could provide to help in this preparation for the additional surge and whether that support is in terms of human	ALL	**ACTION:** a) Jurisdictions can provide their summary to the VVWG email account. A reminder email will be sent out.

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Agenda Item	Description	Lead	Further Actions or Completed
- Use of COVISHIELD (Astra Zeneca) vaccine in Canada: Any initial observations from vaccination sites and at provincial level re AEFIs? - Collection of AEFIs of concern	resources (i.e. public health officers supporting vaccine safety) or financial to help prepare for the surge. • Four provinces, BC, MB, ON, and SK provided their summaries. The remaining jurisdictions will provide their summaries via email to the VVWG email inbox. ➢ Please see Appendix A for the summary from each jurisdictions.		
9. Confirm Next Call	a) Next call: March 25, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, March 25, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Federal Co-Chair), **BC:** [redacted] **MB** [redacted] **NB:** [redacted] **NS** [redacted] **NT:** [redacted] **NU** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **QC** [redacted] **SK** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **DND:** Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Kathleen Eng, Battouli Said Salim, Deborah Danoff, Sophie Sommerer, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Eugenie Samson, Theresa Procter, Tracy Freeland, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Jamal Ahmadian-Yazdi, Alexander Szumillas, Jasminka Draca, Karen C. Roberts, [redacted] Natalia Abraham,

Regrets:
NL: [redacted] **PE** [redacted] **YT:** [redacted] **CANVAS:** [redacted] **FNIHB:** Kim Daly,

ACTION ITEMS

1. Action Item Updates

i) CAEFISS Analysis
- Health Canada sent out the definition of **medically important event** to VVWG and the criteria that is used to classify their AEFIs as medically important events.
- PHAC sent out the definition of **serious medically important** to VVWG.

ii) AstaZeneca hold in EU
- Health Canada provided a list of other countries that have been approved to use COVISHIELD to VVWG.

iii) Roundtable
- Some jurisdictions provided their summary of their strategies, activities, and capacity increases are being planned /used within provinces and territories as well as what support they require from PHAC.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of March 18, 2021 RoD	a) Agenda was approved with no additional items. b) RoD was reviewed. Amendments can be provided to Carmen Salinas by end of day on March 26, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoD to Carmen Salinas by end of day on March 26, 2021 to approve and finalize the RoD from March 18, 2021.
2. Weekly On-line COVID AEFI Report	a) Allison provided a brief summary of the Weekly on-line COVID AEFI Report. The report will be posted on March 26, 2021.	Allison Yeung	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to March 19, 2021. • MB noted that Moderna has a greater rate for non-serious AEFIs. Is there a way to superimpose confidence intervals to see if there is a significant difference? - PHAC can incorporate the confidence intervals in next week's slides and PHAC will also report back later to see if it is statistically significant to VVWG. PHAC will send out an email tomorrow to VVWG	Karin Johnson	**ACTION:** a) PHAC will provide the most frequently reported AESIs to VVWG after the meeting. b) PHAC can incorporate the confidence intervals in next week's slides and PHAC will also report back later to see if it is statistically significant to VVWG. PHAC will send out an email tomorrow (March 26, 2021) to VVWG. c) Following the VVWG meeting, PHAC confirmed that, as of March 25, 2021, 6.5% of AEFI reports in CAEFISS were missing LOT number for the COVID vaccines.
4. AstraZeneca - Latest data from CAEFISS/CVD - Risk communication/update to PM (HC)	**a) Latest data from CAEFISS/CVD** - Natalia Abraham from PHAC provided an update on AstraZeneca.	Natalia Abraham Jhona Rose Joseline Zafack	**ACTION:** a) PHAC will ask [redacted] from CANVAS if she can present at next

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Agenda Item	Description	Lead	Further Actions or Completed
- Update on vaccine guidance(NACI)	• Natalia provided an update on our numbers that have been drawn from CAEFISS with regards to thrombosis and hemorrhagic events. • PHAC reviewed more detailed case information that came out of Europe which helped form their search strategy • Natalia presented some of the key terms that were extracted from cases that came out of Europe. The definitions that were used to extract from CAEFISS were quite broad and far reaching for thrombotic events. (I.e. cerebral venous thrombosis, cerebral venous sinus thrombosis, sagittal thrombosis, etc.) • Cardiac events are under review (cardiac thrombosis/embolus) • Cases are still very low in Canada for thrombotic events. • Canada has no cases of AstraZeneca **Comment:** • [redacted] commented that events that would typically be reported in the ER, non-traditional health mechanisms, etc. how do we make sure that these cases are being caught. • Susanna from PHAC noted that it would be good to hear from PTs as to what is happening on their end regarding this issue. (i.e. Are physicians being made aware that they should be requesting a vaccine history from the patient)? To be discussed further at the roundtable. b) **Risk Communication/update to PM - Sophie Sommerer from Health Canada provided an update.**		week's VVWG meeting the results of the active surveillance system and if they have also seen any of these cases. b) Health Canada will send out questions to VVWG to understand how this is being treated in each jurisdiction and whether the reports that you are collecting and those that are being provided to PHAC would identify the specific version of the vaccine. (Patient information card or second dose card was produced that allows the identification of AstraZeneca versus COVISHIELD) c) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	• The version of the AstraZeneca Vaccine used in Canada is not the same vaccine used in Europe. • Canada uses the COVIDSHIELD vaccine, which is manufactured in India. • The COVISHIELD vaccine and the AstraZeneca vaccine are considered interchangeable and comparable even though they received separate authorizations. • Health Canada is considering if a signal is seen in one vaccine then it should be considered for the other. • Health Canada is working closely with other regulators • The reports that have been received so far some have identified AstraZeneca while others have identified COVISHIELD. COVISHEILD is the only one currently being used in Canada but both versions will eventually be available in Canada. • The AstraZeneca vaccine coming from the US to Canada was manufactured in the US. The shipment coming from the US will arrive next week (week of March 29, 2021) in Canada but will be stored until it is approved. • [redacted] inquired about what data sources are being used by Health Canada (HC) - HC noted that manufacturers provide safety reports both domestic and foreign (monthly safety summary reports are also provided)		

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Agenda Item	Description	Lead	Further Actions or Completed
	- HC looks at what the international experience is with their vaccines using these reports to cross reference with Canada - HC works with PHAC and CAEFISS - HC networks/collaborates with international regulatory bodies - HC is able to get access from other regulators (i.e. MHRA) - Have access to foreign reports that come into Canada Vigilance. - Looking at consultations with experts within Canada to evaluate the mechanism and what is the type of advice that should be provided, what are the symptoms that should be the focussed **c) Update on Vaccine Guidance** – Joseline Zafack from PHAC provided a brief summary. • NACI had a meeting this week regarding the ongoing safety signal identified with AstraZeneca • A statement will be released in early April (before April 10, 2021) on what the recommendations would be.		
5. National Vaccine Management IT Platform (NVMIP)	a) Alex Bourque provided a presentation on the National Vaccine Management IT Platform (NVMIP). • The main concept of this platform is that it is a new tool designed to enable immunization coverage and safety tracking across Canada. **BC** inquired who would have access to the features of this dashboard/system.	Alex Bourque	**ACTION:** a) For further information on the VaccineConnect IIS Solution or to schedule a demo, VVWG members can contact: cassandra.nagy2@canada.ca

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Agenda Item	Description	Lead	Further Actions or Completed
	- Alex noted that this would be an internal tool for public health experts. Each organization would be able to deem appropriate access. - This system is not open to the public. **MB** inquired if this system is for the pandemic only. They also inquired if CAEFISS and Canada Vigilance will be merging. - Alex noted that this system will be ongoing and is not just for the pandemic response. - They are looking to see if this will be feasible. A lot of research needs to be conducted to assess the feasibility of merging CAEFISS and Canada Vigilance. **HC** inquired who would be the data holder. Will the federal government have access and what is the timeline for completion? - Alex noted that with respect to the data holder, today when it comes to coverage information, spread sheets are submitted to his team through an excel approach and it is manually uploaded to databases. The data holder would not change in this regard. - From an accessibility requirement, where access is needed in the Federal Government while adhering to data sharing agreements, requirements, etc. - From a provincial/territorial perspective, they are working out with each province and territory how to enable that access and who should have access. - In respect to timelines, they are moving quickly on this. They want to onboard provinces and territories when and where they see that they can find an opening. They		

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Agenda Item	Description	Lead	Further Actions or Completed
	are working with external stakeholders as well. They are mapping out their next phases and their next releases. [redacted] inquired if there will be a cost for Province and Territories? Is HC covering 100% of the cost? - The funding will be covered by the Federal Government (PHAC). - When it comes to integration, they will need to work with the PTs. - There are no licensing costs. [redacted] inquired how this is above and beyond CAEFISS. Why replace CAEFISS? Is this not a duplication of systems? Why would [redacted] buy into this system when they already report into CAEFISS? - This system will be integrated into CAEFISS. CAEFISS is an older system and they are looking to modernize it and for it to still be part of the IIS. - We pull information from CAEFISS and put it into the IIS. - Not all PTs submit electronically. They would like to move in a direction into a more modern cloud based solution that can grow and evolve with the needs that are identified in a better and more agile way than CAEFISS is currently configured. - This is working in collaboration with CAEFISS to have one immunization system that takes in both coverage and safety data. - It is not a duplication of systems. [redacted] inquired about the data sharing. This is not an easy process. What types of supports and		

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Agenda Item	Description	Lead	Further Actions or Completed
	experience they have had with other jurisdictions and working through some of the data sharing agreements. - This is on their radar. It is still in the technical feasibility study phase. - On the coverage side, they are already ingesting this data. - It was acknowledged that with more integration this becomes an issue. - PTs determine who/how their data is shared so it will work with each PT. **MB**		
8. Roundtable - Update on thrombotic events from jurisdictions - Experience with COVISHIELD vaccinations - What are jurisdictions doing to raise awareness of need to ask about vaccine history for people presenting thrombotic events in ERs and clinicians	a) Please see Appendix A for a summary of responses from jurisdictions from the roundtable discussion.	ALL	**ACTION:** a) No action
9. Confirm Next Call	a) Next call: April 1, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 6, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC** [redacted] **MB:** [redacted] **NB:** [redacted] **NL:** [redacted]
NS: [redacted] **NU** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted] **PE:** [redacted]
[redacted] **QC** [redacted] **SK:** [redacted] **YT** [redacted]

Liaison Members in Attendance:
BRDD: Robert Pless, **DND:** Marie-Christine Lamontagne **FNIHB:** Montana Massicotte, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Kimberley Hutchings, Theresa Procter, Carmen Salinas, Sarah Spruin, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Jamal Ahmadian-Yazdi, Karen C. Roberts, [redacted] Natalia Abraham, Natalie Dayneka, Amrit Boese, Erica Loughlin, Jean Nkanza, Megan Jackman, Shihka Saxena, Karen Roberts, [redacted] Olesia Bissett, **CANVAS:** [redacted]

Regrets:
NT: [redacted] **CSC:** Samar Sarkesh

ACTION ITEMS

1. Action Item Updates

i) AstraZeneca Update

Some jurisdictions have provided their input to the TTS case definition. We still have not received responses from all jurisdictions. Responses are due back to PHAC by Friday, May 7, 2021

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD April 29, 2021	a) Agenda was approved with one additional agenda item added - "**the use of epinephrine in the case of anaphylaxis cases**". b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on May 7, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on May 7, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Allison provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to April 30, 2021. The update and the embargoed report will be posted on May 7, 2021 by the end of the day. • Two changes have been made to the report. PHAC has added tenure age groups to give a more granular view of the age groups and the second change is introducing rates by age group and by age group and sex.	Ashley Weeks	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a brief summary of the CAEFISS Weekly Report. The data provided is up to April 30, 2021.	Karin Johnson	**ACTION:** a) The CAEFISS Analysis report will be posted on CNPHI after the meeting.
4. CANVAS Update	a) [redacted] provided an update on CANVAS up to May 5, 2021. The report has been posted to CNPHI. • [redacted] noted that they might be seeing a signal on Bell's Palsy in their data. She would like to discuss this further at next week's meeting as they are seeing an increase in events particularly from 50 – 64 years of age.	[redacted]	**ACTION:** a) Bell's Palsy will be added to the next week's meeting agenda for further discussion with jurisdictions.
5. AstraZeneca Update - TTS case definition update	a) Natalia And Susanna provided an update on **Thrombocytopenia Thrombosis Syndrome (TTS)** definition that they are presenting to the Special Advisory Committee (SAC) later in the day.	Natalia Abraham/ Susanna Ogunnaike-Cooke/	**ACTION:** a) The presentation was posted to CNPHI prior to the start of the meeting.

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- Summary of TTS cases in Canada - Summary of international findings	• Susanna and Natalia are working on getting a concurrence on a case definition at the SAC meeting • They are also presenting an update around cases and rates. b) Jhona Rose provided an International regulatory update and a Health Canada update. • HC did receive the risk management plan in house for AstraZeneca and they are currently reviewing the pharmacovigilance in risk minimization activities that are listed in the document. HC is also monitoring it through the monthly safety reports. • Myocarditis activities is being monitored internationally. The cumulative data is intended to be submitted to HC for review. • Facial paralysis (Bell's Palsy) has been seen in the monthly safety report. This is being followed up with the company about the cases and HC will share the cumulative assessment.	Jhona Rose (HC)	b) No action
6. Background Rates Update	a) Sarah provided an update on the background rates. • Preliminary background rates have been completed for coagulation disorders, anaphylaxis, bell 's palsy and myocarditis.	Sarah Spruin	**ACTION:** a) Sarah will look further into the rates and how they compare to the FDA and EMA rates.
7. Group Question - Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization	a) Yukon has asked the following question to VVWG: • Yukon only has the Moderna vaccine to administer. They have noticed that many of their adverse events were of inflammatory nature and some of the more serious events were of a cluster of inflammatory nature. Is this something that is being seen in other areas? Specifically, the Yukon has seen a case of myocarditis, polymyalgia rheumatic, polyarthropathy, and uveitis. All of these have been in patients who had no pre-existing history and most	[redacted]	**ACTION:** a) The question will be sent out via email to VVWG to give time to research and provide a response at next week's meeting.

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	were young. The Yukon has also seen other inflammatory ones that are under investigation. They have also seen some significant flare-ups of autoimmune disease or inflammatory disease such as, MS and possibly Lupus. • YK is wondering if this is a trend that is being seen in other jurisdictions and if there is any other information that can be drawn from this. They would like to know if this has been seen in the first dose and should they receive their second dose. • YK would like to start a discussion and are looking for guidance to give their providers		
8. Roundtable - PT observations of AEFIs with AZ/COVISHIELD	a) BC asked about the use of epinephrine in its anaphylaxis cases and the proper recording of these events. • BC is suggesting updating the form to add a box of whether or not epinephrine had been administered. • This could be added to the allergic section of the form. This will allow to separate out true anaphylaxis cases versus reports that might not even be allergic in nature but can still see that the epi was given so that they were managed as anaphylaxis. • BC would like to know what PTs think. Are they supportive of such change? b) The roundtable item "**PT observations of AEFIs with AZ/COVISHIELD**" has been deferred to next week's meeting.	ALL	**ACTION:** a) No action b) The roundtable item "**PT observations of AEFIs with AZ/COVISHIELD**" has been deferred to next week's meeting. This will be added as its own agenda item.
9. Confirm Next Call	a) Next call: May 13, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 13, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
BC [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] [redacted] **(PHO):** [redacted] **PE:** [redacted] **QC:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne **FNIHB:** Montana Massicotte, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Nooshin Ahmadipour, Theresa Procter, Carmen Salinas, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, [redacted] Natalia Abraham, Amrit Boese, Erica Loughlin, Jean Nkanza, Althea House, Bryan Griffin, [redacted] Olesia Bissett, **CANVAS:** [redacted]

Regrets:
AB: [redacted] (Provincial Co-Chair), **NL:** [redacted] **CSC:** [redacted] **BRDD:** Robert Pless, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) CANVAS Update

Bell's Palsy has been added as an agenda item to this week's meeting. This item was discussed during the CANVAS update.

ii) Background Rates Update

Sarah Spruin is still looking into creating a document comparing Canada's background rates to FDA and EMA background rates.

iii) Group Question - Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization

The question from the Yukon was sent out to VVWG on May 10, 2021 for PT's to review and provide a response at the May 13, 2021 VVWG meeting.

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Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting a) Review and approval of agenda b) Review of RoD May 6, 2021	a) Agenda was approved with no additional agenda items. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on May 14, 2021.	Amanda Shaw	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on May 14, 2021 to approve and finalize the RoD.
2. CANVAS Update	a) [redacted] provided a presentation on "**CANVAS: Active Safety Surveillance for COVID-19 Vaccines: Bell's Palsy**." The presentation will be posted to CNPHI after the meeting.	[redacted]	**ACTION:** a) The presentation will be posted to CNPHI after the meeting.
3. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to May 7, 2021. The update and the embargoed report will be posted on May 7, 2021 by the end of the day.	Ashley Weeks	**ACTION:** a) No action
4. CAEFISS Analysis	a) Karin provided a presentation of the CAEFISS Weekly Report. The data provided is up to May 7, 2021.	Karin Johnson	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting. b) Karin will report back at next week's VVWG meeting regarding those specific lot numbers for Bell's Palsy.
5. AstraZeneca Update - TTS case definition update - Summary of TTS cases in Canada	a) Natalia provided an update on **Thrombocytopenia Thrombosis Syndrome (TTS)** case definition. • The case definition was approved by the Special Advisory Committee (SAC) last week. This is aligned with the Brighton Collaboration case definition for	Natalia Abraham/ Jhona Rose (HC)	**ACTION:** a) The presentation will be shared with VVWG late today or tomorrow (May 14, 2021).

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Agenda Item	Description	Lead	Further Actions or Completed
- Summary of international findings	Thrombosis with Thrombocytopenia Syndrome (TTS) following vaccination. b) Jhona Rose provided an International regulatory update and a Health Canada update. • There is an interest to have a summary of the case definitions that are published internationally in comparison to Canada's and to have a side-by-side comparison, which is being considered to be put in place. • HC is waiting for the company's data for the cumulative data for the TTS coming from AstraZeneca, which is supposed to be received in the next few days.		b) No action
6. PT observations of AEFIs with AstraZeneca/COVISHIELD	a) PTs provided their observations of AEFIs with AstraZeneca/COVISHIELD. The responses have been captured along with agenda item 7 as Appendix A.	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide a response will be sent an email to obtain their response.
7. Group Question - Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization	a) Yukon has asked the following question to VVWG: Yukon is noting a cluster of significant inflammatory illnesses with onset within 2 weeks of Moderna vaccination, often young persons, often after 2nd dose. Also, exacerbations of pre-existing inflammatory diseases. As a small population, it is unlikely of statistical significance above baseline rates. Are similar trends being seen elsewhere in Canada or the world? Particularly of interest with mRNA vaccines as Yukon only has Moderna. • Diseases of inflammatory or autoimmune nature. Eg, inflammatory arthritis, myositis, connective tissue	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide a response will be sent an email to obtain their response.

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Agenda Item	Description	Lead	Further Actions or Completed
	diseases, inflammatory bowel disease (eg. crohns Ulcerative colitis), neuritis or neurological diseases that have inflammatory process (eg. MS, menigio/encephalopathies, myelitis, GBS, MG, possibly bell's palsy), immune renal disease, uveitis, perimyocarditis. Inflammations or autoimmune diseases of other organ systems not listed and of significant impact to individual *The responses have been captured along with agenda item 6 as Appendix A.		
8. Roundtable	a) No items were discussed during the roundtable discussion.	All	**ACTION:** a) No action
9. Confirm Next Call	a) Next call: May 20, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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APPENDIX A

JURISDITIONS	Question 1: PT observations of AEFIs with AstraZeneca/COVISHIELD	Question 2: Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization
AB	N/A	• [redacted]
BC	• The rates of serious AEFI reports have been very consistent between the viral vectors and the mRNA vaccines. • BC has seen more reports for different thrombotic events, which is probably following just the media of those events occurring in Europe (strokes, etc.). These have been occurring for all the vaccines and not just AstraZeneca and COVISHIELD.	• These are hard to find in their data. BC has had some of the conditions such as, Bell's palsy. They are occurring but BC cannot provide a numeric rate for these conditions.
MB	• [redacted] • [redacted]	• [redacted] • There are also cases of Bell's Palsy following AZ, but their occurrence is consistent with background rate.
NB	• COVISHIELD has a higher rate compared to AstraZeneca, which is also noticeably higher compared to Pfizer and Moderna, which are mostly equivalent in terms of serious.	• NB has had 3 cases of Bell's Palsy and one case of myeloradiculopathy
NL	N/A	
NS	N/A	
NT	• NT is not using the AstraZeneca/COVISHIELD product	• Nothing of significance. They have had the occasional incidence but nothing that has standing out.

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JURISDITIONS	Question 1: PT observations of AEFIs with AstraZeneca/COVISHIELD	Question 2: Inflammatory flare-ups of autoimmune disease post COVID-19 Immunization
NU	• NU is not using the AstraZeneca/COVISHIELD product	• They have not noted any flare-ups of inflammatory disease at this time.
ON	• ON is seeing a higher [redacted] reporting rate for COVISHIELD/AstraZeneca. As of May 10, 2021, ON has seen 21 reports that met their [redacted] definition.	• ON has not had a chance to look at this yet.
PE	N/A	
QC	N/A	
SK	• There is no difference in the adverse events that they have seen coming compared to Pfizer or Moderna	• SK has had a few GBS cases for all of the vaccines. • They have had a few more reports on thrombotic issues but a lot of them were deemed as not being related to the vaccine or somebody had underlying conditions and they were not diagnosed as a TTS or they did not require that degree of clinical consultation.
YT	• YK is not using the AstraZeneca/COVISHIELD product	• [redacted]

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 20, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair) [redacted] **BC:** [redacted] **MB:** [redacted] **NB:** [redacted] **NL** [redacted] **NS** [redacted]
NT: [redacted] **NU:** [redacted] **ON: (MOH)** [redacted] **(PHO):** [redacted]
PE: [redacted] **QC:** [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff,

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Theresa Procter, Carmen Salinas, Jocelyn Bougie, Andrew Atabe, Allison Yeung, Ashley Weeks, [redacted] Natalia Abraham, Amrit Boese, Erica Loughlin, Jean Nkanza, Althea House, Bryan Griffin, [redacted] Olesia Bissett, Lucas Gursky, Bikash Chudal, Carmen Leung, Joseline Zafack, Yvette Adonis, Pauline Barbeau, **CANVAS:** [redacted]

Regrets:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **FNIHB:** Melanie Knight, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. Action Item Updates

i) CAEFISS Update

Karin reported at today's meeting the specific lot numbers that are associated with Bell 's palsy following the administration of Pfizer (i.e. Lot # ER1742).

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with no additional agenda items. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on May 21, 2021.	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD May 13, 2021			end of day on May 21, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to May 14, 2021. The update and the embargoed report will be posted on May 14, 2021 by the end of the day.	Ashley Weeks/Allison Yeung	**ACTION:** a) No action
3. CAEFISS Analysis	a) Karin provided a presentation of the CAEFISS Weekly Report. The data provided is up to May 14, 2021. • Karin presented on questions that were raised at last week's meeting as well as information requests. • PHAC examined the Brighton Collaboration case levels on conditions discussed last week for Bell 's palsy, GBS and Myocarditis. Some reports are still under review and some are waiting for additional information and cannot be assessed until then. • [redacted] has had many cases of Bell's Palsy • Karin's presentation will be posted on CNPHI after the meeting.	Karin Johnson	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting.
4. CANVAS Update	a) Julie Bettinger provided an update on CANVAS. The report has been posted on CNPHI.	[redacted]	**ACTION:** a) No action
5. TTS, Myocarditis updates	a) Amanda provided a presentation on myocarditis following Pfizer vaccine. • This was initially presented to VVWG a few weeks ago.	Amanda Shaw/Natalia Abraham	**ACTION:** a) Amanda's presentation will be posted to CNPHI after the meeting.

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Agenda Item	Description	Lead	Further Actions or Completed
	• An international potential safety signal was raised following the Pfizer vaccine initially in Israel and then in the United States primarily in young males after dose 2. • Currently, we do not have a large amount of dose 2 AEFI's to report. • In our regular safety signal detection analysis, myocarditis alone was showing up as being a slightly higher count of cases compared to in Pfizer, COVID vaccines compared to non-COVID vaccines from the past in CAEFISS. • Brighton Collaboration case definition is under development. Currently, the Medra terms myocarditis and pericarditis are being including in our case definition. • Observed data versus expected data is much lower than expected at this time for all vaccines therefore, this is not a safety signal in Canada at this time but monitoring will be continued b) Natalia provided an update on TTS. • The SAC approved version of the Canadian Case definition for thrombosis with thrombocytopenia syndrome has been presented and submitted. • A new version of the Brighton Collaboration Case Definition that came out two days ago - Subtyping for heparin exposure added - Since we have access to PF4 testing in Canada this may not be as relevant to Canada • Discussions will continue regarding this matter • The UK has just posted updated information from the UK on rates of Thrombosis with Thrombocytopenia after first and second doses of AstraZeneca		b) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	(Coronavirus vaccine - weekly summary of Yellow Card reporting - GOV.UK (www.gov.uk)) Data up to May 12, 2021: • **After 1st dose:** 12.3 per 1M doses (or 1 in 81,000 first doses administered) • **After 2nd dose**: 15 cases in an estimated 9M vaccinations (or 1 in 600,000 second doses administered) – this is higher than the previous estimate of 1 in 1 million second doses, and similar to what we observed in March/April with first doses, the rate seems to be increasing with time.		
6. ACCA Update	a) Natalie provided an update on ACCA. • Last week we presented to the VP and DG and support was approved and the proposal is now a plan. • We started a PHAC internal planning group meeting. They do have a volunteer for an internal chair. • At the first meeting a decision was made to focus on the development criteria for recommending a case. • Next steps: - meetings will continue with individuals from provinces and territories - need to focus on the confidentiality and privacy issues • [redacted] Any information we share with VISP should be considered as in the public domain. External members are not obligated to participate in VISP but they should also not be prevented in participating.		

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Agenda Item	Description	Lead	Further Actions or Completed
	• Hoping to have the first meeting before the start of summer		
7. Tracking of Mixed Vaccine AEFIs	a) Kimberley provided a summary of tracking of mixed vaccine AEFIs. • Discussions and questions have been in place regarding whether we can report and monitor the AEFIs of individuals for their second dose of the COVID vaccine in particular those that received a vaccine that is different from their first dose (i.e. 1st dose AstraZeneca, 2nd dose Pfizer).We want to make sure we are able to track this. • This has been addressed on the updated National AEFI Form. • While the National AEFI form is being finalized, we are recommending that this information can be entered in section 4C. • We have been asked if we are going to be able to compare AEFIs reported after the 2nd dose to any that have been reported to the 1st dose (regardless of mixing vaccines). Since we do not have identifiers, we cannot link this on our end. • Some potential options are: 1. Have PTs link it in their database if this is feasible; or 2. Have PTs provide us with the unique identifiers to link it on our side; or 3. Have the reporter, if there was a previous AEFI, to the first dose and have them fill out those details in the AEFI in the second report.	Kimberley Hutchings	**ACTION:** a) Add to next week's agenda: How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules? PTs are to prepare with how to handle this in their own jurisdiction.
8. Group Question – Have jurisdictions seen cases of retinal vein	a) PTs provided their responses to the two group questions. These have been captured in Appendix A.	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide

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Agenda Item	Description	Lead	Further Actions or Completed
thrombosis following AstraZeneca? - Have jurisdictions seen cases of adverse events of vaccine associated enhanced disease?			a response will be sent an email to obtain their response.
9. Roundtable	a) MB noted that a correction needs to be made to the RoDs from May 13, 2021. MB will send the correction via email later today. b) [redacted] noted that the final Brighton Collaboration VAED definition has been published. Here is the link to the publication: https://www.sciencedirect.com/science/article/pii/S0264410X21000943?via%3Dihub	All	**ACTION:** a) MB will provide a correction to the May 13, 2021 RoD's via email later today to be amended.
10. Confirm Next Call	a) Next call: May 27, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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APPENDIX A

JURISDITIONS	Question 1: Have jurisdictions seen cases of retinal vein thrombosis following AstraZeneca (blurred vision)?	Question 2: Have jurisdictions seen cases of adverse events of vaccine associated enhanced disease?
AB	• No, AB has not seen any of these cases.	• No, AB has not seen any cases or adverse events.
BC	• No, BC has not seen any of these cases.	• No, BC has not seen any cases or adverse events.
MB	• No, formal AEFI reports have been received yet.	• [redacted]
NB	• No, NB has not seen any of these cases. However, visual impairment has been seen by an optometrist in NB. The doctor has reported that some of his clients have experience blurred vision or visual impairment following the COVID vaccine. This has not been reported yet as an AEFI. NB will look into this matter further.	• No, NB has not seen any cases or adverse events.
NL	N/A	N/A
NS	• No, NS has not seen any of these cases.	• No, NS has not seen any cases or adverse events.
NT	• NT is not using AstraZeneca therefore; they have not seen any of these cases.	• No, NT has not seen any cases or adverse events.
NU	• NU is not using AstraZeneca therefore; they have not seen any of these cases.	• No, NU has not seen any cases or adverse events.
ON	• No, ON has not seen any of these cases. They have not conducted a systematic search for blurred vision yet.	• No, ON has not seen any cases or adverse events.
PE	• N/A	• N/A
QC	•	
SK	• No, SK has not seen any of these cases.	• No, SK has not seen any cases or adverse events.
YT	• YT is not using AstraZeneca therefore; they have not seen any of these cases.	• No, YT has not seen any cases or adverse events.

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, June 3, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC** [redacted] **MB:** [redacted] **NB:** [redacted] **NL:** [redacted] **NS:** [redacted]
NT: [redacted] **NU:** [redacted] **ON: (PHO):** [redacted] **PE:** [redacted]
QC: [redacted] **SK:** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff, Kathleen Eng, **FNIHB:** Cynthia Tardivel, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Karin Johnson, Kimberley Hutchings, Carmen Salinas, Theresa Procter, Jocelyn Bougie, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks [redacted] Natalia Abraham, Jean Nkanza, Yvette Adonis, Helen Anyoti, Nooshin Ahmadipour, Pauline Barbeau, Wissam Hussein, Ria Sharma, Alexa Dallaire, Sarah Spruin, Natalie Ward, Emmanuella Ngebunui Atanga, Carmen Leung, Melissa Hunt, Olesia Bissettt, Megan Jackman, Mona Yazdani, Liam John Gordon, Christina Jensen, **CANVAS:** [redacted]

Regrets:
BRDD: Robert Pless, **CSC:** Samar Sarkesh

ACTION ITEMS

1. **Action Item Updates**
   - **No updates to report on action items.**

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with no additional agenda items. b) RoDs were reviewed. Amendments can be	[redacted]	**ACTION:** a) No action b) Members can provide changes or updates to the RoDs to Carmen Salinas by

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD May 27, 2021	provided to Carmen Salinas by end of day on June 4, 2021.		end of day on June 4, 2021 to approve and finalize the RoD.
2. CANVAS Update	a [redacted] provided an update on CANVAS. • For any questions regarding CANVAS, please contact [redacted] directly.	[redacted]	a) No action
3. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to May 28, 2021.	Ashley Weeks/Allison Yeung	**ACTION:** a) The update and the embargoed report will be posted on June 4, 2021 by the end of the day.
4. CAEFISS Analysis	a) Pauline provided a presentation of the CAEFISS Weekly Report. The data provided is up to May 28, 2021. The following items were covered: • Serious and non-serious reports by jurisdiction • Reason for seriousness by vaccine Pauline provided status updates on previous AEFIs that were discussed: • **Bell's palsy** – the medical review team is currently in the process of reviewing the cases and assigning the BCD criteria • **Sensorineural hearing loss (SNHL)** – currently in the process of fine tuning the definition to most accurately capture the cases of SNHL • **Menstrual events** – One case has been identified in CAEFISS since last week's presentation	Pauline Barbeau	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting. b) Karin has asked if PTs can forward the definitions that they are using to identify SNHL to the VVWG email inbox.
5. Myocarditis update	a) Natalia provided a presentation on myocarditis.	Natalia Abraham	**ACTION:** a) Natalia's presentation will be posted to CNPHI after the meeting. b) A Communique will be sent out to VVWG members after the meeting relating to myocarditis and pericarditis

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Agenda Item	Description	Lead	Further Actions or Completed
			following vaccination with mRNA COVID-19 vaccines which can be shared with health practitioner networks or that can be used to inform content for other documents that one may be developing on this topic.
6. TTS update	a) Amanda provided a presentation on TTS. • Natalia shared the following link on frequency of positive anti-PF4/polyanion antibody tests after COVID-19 vaccination with ChAdOx1 nCoV-19 and BNT162b2: https://pubmed.ncbi.nlm.nih.gov/33988688/	Amanda Shaw	**ACTION:** a) Amanda's presentation will be posted to CNPHI after the meeting.
7. GBS update	a) Natalia provided a presentation on GBS. • No clear signals internationally but the EMA and other jurisdictions are investigating cases	Natalia Abraham	**ACTION:** a) Natalia's presentation will be posted to CNPHI after the meeting.
8. Brighton Collaboration Update	a) [redacted] provided presentation on the Brighton Collaboration ABC Tool 2.0. • The ABC tool will be going live soon. • [redacted] provided a demo on how it works • One pagers can be downloaded (pictorial algorithm)	[redacted]	**ACTION:** a) [redacted] will share the link to the Brighton Collaboration ABC tool after the meeting.
9. Group Question - Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine?	a) PTs provided their responses to the group question. These have been captured in Appendix A.	All	**ACTION:** a) Please see PT responses in Appendix A.
10. Roundtable -Are P/Ts reporting symptoms compatible with ISRR as AEFIs? [(e.g.	a) PTs provided their responses to the roundtable question. This has been capture in Appendix B.	All	**ACTION:** a) Manitoba asked a question - **Are PTs seeing MS exacerbation following mRNA**

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Agenda Item	Description	Lead	Further Actions or Completed
vasovagal reactions, hyperventilation, and functional neurological symptoms (e.g. weakness, non-epileptic seizures)]			**vaccines?** This will be addressed at next week's VVWG meeting. b) BC asked a question - Has anyone received reports of very unusual paresthesia's - all over body, burning? This will be addressed at next week's VVWG meeting.
11. Confirm Next Call	a) Next call: June 10, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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APPENDIX A

JURISDITIONS	Question 1: How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules?	Question 2: Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine?
AB	[redacted]	[redacted]
BC	• No link done in Panorama • Not the usual operating procedure • Would need to put in comment area • No way of determining if second dose is the same • Would need Client Immunization Record	• BC has received 4 reports and they have been submitted to CAEFISS
MB	• Able to link report • Duplicate of the Client ID • Could send Event ID	• MB has received 2 reports (1 Moderna and 1 Pfizer) • MB has received one case of tinnitus from the Pfizer vaccine.
NB	• Currently sending PDF with Client ID • Working on sending line list in excel	• No reports have been received
NL		• No reports have been received
NS	• Panorama could pose a challenge • Would need to work with the IT Team • Could send manually	• No reports have been received
NT	• Not using Panorama • Can determine if a person experienced a previous AEFI • Would need to investigate how to report it	• No reports have been received
NU	• Currently only using Moderna but small team could pull the information together manually	•
ON	• Could use Client ID • Would need to investigate how to send to PHAC • Would need Client Immunization Record	• ON has received 1 report but they have not had a chance to do a systematic search of their data for this event.
PE		• *No reports have been* received

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JURISDITIONS	Question 1: How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules?	Question 2: Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine?
QC		• Possibly have 2 cases but will confirm
SK	• Not currently in Panorama • Cannot send Event ID • Could put manually in brackets what first dose was • Client Immunization Record would be needed	• SK has received 1 report.
YT	• Panorama could pose a challenge • No link to previous doses • Could pull a report and get this information if required	• [redacted]

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APPENDIX B

JURISDITIONS	QUESTION: Are P/Ts reporting symptoms compatible with ISRR as AEFIs? [(e.g. vasovagal reactions, hyperventilation, and functional neurological symptoms (e.g. weakness, non-epileptic seizures)]
AB	[redacted]
BC	• BC has been seeing these events. Anaphylaxis reports are often anxiety related reactions, etc. BC only reports if there is an injury or managed as anaphylaxis.
MB	• MB has 2 cases of syncope following Pfizer and one case following AstraZeneca. Two cases of vasovagal reaction following Pfizer.
NB	• NB has 2 cases of syncope (1 following COVISHIELD and 1 following Pfizer)
NL	• NL is definitely seeing these events (vasovagal reactions, hyperventilation, and functional neurological symptoms). They are experiencing high volumes of AEFIs at this time.
NS	• NS is the jurisdiction that asked the question. No response required.
NT	• NT has been seeing these events. Only reporting if it meets case definition. NT goes by AB's case definition for reporting.
NU	• N/A
ON	• ON does not have a case definition for stress related response but ON does have one for syncope with injury. If stress related response are reported they are likely captured under their database under "**Other**."
PE	• PE is seeing a high volume of AEFIs. PEI is also seeing vasovagal reactions and syncope but unable to report the numbers.
QC	• QC agrees with BC's approach
SK	• SK has been seeing these events. They are not reporting syncope without injury. SK has had a couple of non-epileptic seizures reported and some weakness reports as well. These have all been submitted.
YT	• YK has not seen any reports. They just started vaccinating the 12-18 year olds so they may see some reports • YK has seen several vasovagal and syncope but YK only reports if there is injury and there have been none of these. [redacted]

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, June 10, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC:** [redacted] **MB** [redacted] **NB:** [redacted] **NL:** [redacted]
NS: [redacted] **NT:** [redacted] **NU:** [redacted] **ON: (MHO):** [redacted] **(PHO):** [redacted]
[redacted] **PE:** [redacted] **QC:** [redacted] **SK** [redacted] **YT:** [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff, Kathleen Eng, **FNIHB:** Melanie Knight

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Karin Johnson, Kimberley Hutchings, Carmen Salinas, Theresa Procter, Jocelyn Bougie, Tracy Freeland, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Amrit Boese, [redacted] Natalia Abraham, Yvette Adonis, Helen Anyoti, Nooshin Ahmadipour, Pauline Barbeau, Wissam Hussein, Ria Sharma, Alexa Dallaire, Sarah Spruin, Emmanuella Ngebunui Atanga, Carmen J. Leung, Melissa Hunt, Olesia Bissettt, Megan Jackman, Mona Yazdani, Liam John Gordon, Christina Jensen, Dylan Hegarty, Samantha Guy, **CANVAS:** [redacted]

Regrets:
BRDD: Robert Pless, **CSC:** Samar Sarkesh, **IMPACT:** [redacted] **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   i. **CAEFISS Analysis:**
      - Some responses have been received from PTs regarding which definition they are using to identify SNHL to Karin Johnson. An email reminder was sent out to VVWG members after the meeting today.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with three additional agenda items. 1. Reporting AEFIs in inmates at Correctional Services – what is the process.	Amanda Shaw	**ACTION:** a) Three additional agenda items have been added to the roundtable discussion.

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD June 3, 2021	2. Update on Background rates 3. Myocarditis – update on the Communiqué and clinical guidance. b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on June 11, 2021.		1. Reporting AEFIs in inmates at Correctional Services – what is the process. 2. Update on Background rates 3. Myocarditis – update on the Communique and clinical guidance. b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on June 11, 2021 to approve and finalize the RoD. c) Karin will send out an email to VVWG requesting jurisdictions to provide how they are defining cases of sensorineural hearing loss (SNHL) after the meeting.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to June 4, 2021.	Ashley Weeks/Allison Yeung	**ACTION:** a) The update and the embargoed report will be posted on June 11, 2021 by the end of the day.
3. CAEFISS Analysis	a) Pauline provided a presentation of the CAEFISS Weekly Report. The data provided is up to June 4, 2021. The following items were covered: 1. Death amongst Seniors (65+) (Long Term care / Retirement Nursing Homes vs. Community) 2. SNHL and Tinnitus	Pauline Barbeau	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting.
4. Updates: • Myocarditis • TTS • GBS	a) Amanda provided an update on Myocarditis, TTS and GBS. The updates are up to June 6, 2021. The presentation on these updates will be posted to CNPHI after the meeting.	Natalia Abraham/Amanda Shaw	**ACTION:** a) The presentation will be posted to CNPHI after the meeting.

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Agenda Item	Description	Lead	Further Actions or Completed
5. Updated TTS case definition	a) Natalia provided an update on the TTS case definition. • Some revisions have been made to the Canadian TTS Case definition that had been previously approved by the Special Advisory Committee (SAC) • A request for changes will be sent to VVWG to obtain comments and/or suggestions. This will be forthcoming. • Input will be brought back to CIC or SAC again for approval.	Natalia Abraham	**ACTION:** a) An email will be forthcoming to VVWG members to obtain comments and/or suggestions on the revised TTS Case Definition.
6. Brighton Collaboration Update	a) [redacted] did not have any new updates to share on the Brighton Collaboration.	[redacted]	**ACTION:** a) No action
7. International and Regulatory Updates	a) Jhona provided an update on international public health agency and regulatory meetings. • HC completed reviews of the monthly safety reports. **Moderna** ▪ HC followed up with the company to provide a cumulative assessment for myocarditis, sudden death, hypersonia, and some discrepancies on the information about the estimates for background rate on anaphylaxis. ▪ HC also requested some information on aligning some of the labelling. This is available in their core data sheets. **Pfizer** ▪ Myocarditis – HC requested additional cumulative assessment and also any plan to include any additional post marketing pharmacovigilance activities or any risk minimization or any plan to include in the Canadian product monograph ▪ HC requested information on Facial paralysis	Jhona Rose	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	▪ Other events HC is following up for cumulative assessment including, cases of TTS, cases of seizures, cases of intracranial hemorrhage, and cases of hearing loss **AstraZeneca** ▪ GBS – HC has requested a cumulative assessment and any other activities that require labelling or risk minimization activities ▪ Bell's Palsy / facial paralysis is also being requested by the company **International** ▪ Myocarditis review is ongoing and there are no regulatory actions at this time.		
8. Roundtable – Group Questions 1. Are PTs seeing MS exacerbation following mRNA vaccines? 2. Has anyone received reports of very unusual paresthesia's - all over body, burning?	a) PTs provided their responses to the group questions. These have been captured in Appendix A. b) Additional agenda items added. 1. **Background Rates:** • Sarah Spruin noted that the Background rates have now been posted to CNPHI. • The methodology will be written up at a later date. Sarah will share the Methods paper that she based the observed expectant analysis off of. 2. **AEFI Reporting for Inmates in Correctional facilities:** • CSC, RCMP and Indigenous Services Canada are supposed to be report through their provinces and territories. The only department submitting reports directly to PHAC is DND. • Below is a description and the link on how data should flow including people in Correctional facilities through Public Health.	All	**ACTION:** a) Please see PT responses in Appendix A. b) Canada Vigilance vs CAEFISS and how the data are combined and processed will be presented at next week's VVWG meeting

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Agenda Item	Description	Lead	Further Actions or Completed
	Submitted reports: CAEFISS reports are submitted by public health authorities in provinces and territories, who in turn receive them from local public health units. Provincial and territorial authorities also receive reports from federal authorities that provide immunization within their jurisdiction, including, •the RCMP •Indigenous Canada •Correctional Services Canada Most of these reports are generated by nurses, physicians or pharmacists who provide immunizations or who care for individuals with AEFIs. AEFIs received by National Defence and the Canadian Armed Force are reported directly to PHAC. Here is the link: https://www.canada.ca/en/public-health/services/immunization/canadian-adverse-events-following-immunization-surveillance-system-caefiss.html		
9. Confirm Next Call	a) Next call: June 17, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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APPENDIX A

JURISDITIONS	Question 1: Are PTs seeing MS exacerbation following mRNA vaccines?	Question 2: Has anyone received reports of very unusual paresthesia's - all over body, burning?
AB	• No	• No
BC	• BC definitely has reports for individuals who have a history of MS but they are not necessarily for an MS exacerbation there are other AEFI events.	• BC has had a number of reports of paresthesia. BC has received one report of burning sensation to the large portion of the body.
MB	• MB has received two reports of MS exacerbation. These are patients who have MS, a past medical history of MS. They experienced exacerbation of symptoms following vaccination.	• MB has 10 cases of paresthesia. Mostly with mRNA vaccines. Two are associated with COVID. • No cases of all over body burning.
NB	• No	• No
NL	• No	• No
NS	• No	• No
NT	•	•
NU	• No	• NU has one report of a burning sensation on one side of the scalp. They also had a very swollen cervical lymph node.
ON	• ON has 5 cases of exacerbation of MS. Three following Pfizer and 2 following AstraZeneca vaccine. [redacted]	• ON has noted a few cases immediately after receiving the vaccine but also, the symptoms did not last more than 24 hours therefore, it did not meet the temporal criteria for reporting as anesthesia paresthesia. • ON also had a few cases that occurred a few hours to days after receiving the vaccine. [redacted]
PE		•
QC	• QC has identified at least one case of MS exacerbation (# [redacted] post Moderna).	• There are multiple cases of « Anesthésie/paresthésie généralisée »

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JURISDITIONS	Question 1: Are PTs seeing MS exacerbation following mRNA vaccines?	Question 2: Has anyone received reports of very unusual paresthesia's - all over body, burning?
		and we will need to review all of them to identify if there are cases with comments about burning.
SK	• No	• SK has received one report of a sunburnt feeling on their scalp but no other reports of all over body burning.
YT	[redacted]	[redacted]

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, June 17, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), **BC** [redacted] **MB:** [redacted] **NB:** [redacted] **NS:** [redacted] **NT:** [redacted]
NU: [redacted] **ON: (MHO):** [redacted] **(PHO):** [redacted] **PE:** [redacted] **SK:** [redacted]
[redacted] **YT:** [redacted]

Liaison Members in Attendance:
BRDD: Annick Gauthier, **DND**: Marie-Christine Lamontagne, **FNIHB:** Melanie Knight; **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff, Kathleen Eng

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Karin Johnson, Kimberley Hutchings, Carmen Salinas, Theresa Procter, Jocelyn Bougie, Tracy Freeland, Andrew Atabe, Saundra Houle, Allison Yeung, Ashley Weeks, Amrit Boese, Natalia Abraham, Natalie Dayneka, Yvette Adonis, Helen Anyoti, Nooshin Ahmadipour, Pauline Barbeau, Joseline Zafack, Wissam Hussein, Ria Sharma, Sarah Spruin, Emmanuella Ngebunui Atanga, Carmen J. Leung, Melissa Hunt, Olesia Bissett, Megan Jackman, Mona Yazdani, Christina Jensen, Dylan Hegarty, Samantha Guy, Annie Fleurant, **CANVAS:** [redacted]

Regrets:
NL: [redacted] **QC:** [redacted] **CSC:** Samar Sarkesh, **RCMP:** Roxanne Tauvette

ACTION ITEMS

1. **Action Item Updates**
   i. **CAEFISS Analysis:**
      - Some responses have been received from PTs regarding which definition they are using to identify SNHL to Karin Johnson. An email reminder was sent out to VVWG members after last week's meeting.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting	a) Agenda was approved with one additional agenda item. • Have jurisdictions seen magnetization at the injection site following the Pfizer vaccine?	[redacted]	**ACTION:** a) One agenda item has been added to the roundtable discussion: Have jurisdictions seen magnetisation at

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD June 10, 2021	b) RoDs were reviewed. Amendments can be provided to Carmen Salinas by end of day on June 18, 2021.		the injection site following the Pfizer vaccine? b) Members can provide changes or updates to the RoDs to Carmen Salinas by end of day on June 18, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Ashley provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to June 11, 2021. • There are no new safety signals. One safety signal continues to be monitored and PHAC is also monitoring myocarditis	Ashley Weeks/Allison Yeung	**ACTION:** a) The update and the embargoed report will be posted on June 18, 2021 by the end of the day. b)
3. CAEFISS Analysis	a) Pauline provided a presentation of the CAEFISS Weekly Report. The data provided is up to June 11, 2021. The following items were covered: 1. Capillary leak syndrome 2. Bell's Palsy 3. AEFI reports (12-17 year olds)	Pauline Barbeau	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting. b) Pauline will look into what is the cause of the 5 reported chest pains for the 12-17 year old age group? Is it myocarditis? This will be reported back at next week's meeting.
4. CANVAS Update	a) [redacted] provided an update on CANVAS. The weekly report has been posted on CNPHI.	[redacted]	**ACTION:** a) The CANVAS weekly report has been posted to CNPHI (report up to June 16, 2021).
5. TTS, GBS, Myocarditis Updates	a) Amanda provided updates on TTS, GBS and Myocarditis. The updates are up to June 13, 2021. The presentation will be posted to CNPHI after the meeting.	Amanda Shaw/Natalia Abraham	**ACTION:** a) The presentation will be posted to CNPHI after the meeting.

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Agenda Item	Description	Lead	Further Actions or Completed
6. TTS case definition and heads up alerts	a) Natalia and Susanna provided an update on the TTS case definitions and provided a heads up alerts. • PHAC is seeking comments for the revised Canadian case definition for thrombosis with thrombocytopenia syndrome. This will be presented at next week's CIC meeting. An email was sent out to VVWG earlier today to request comments from members. • PHAC no longer requires a heads up for TTS cases	Natalia Abraham/Susanna Ogunnaike-Cooke	**ACTION:** a) PHAC is seeking comments from members for the revised Canadian case definition for thrombosis with thrombocytopenia syndrome as soon as possible. This will be presented at next week's CIC meeting.
7. CAEFISS Information on second dose AEFIs	a) Kimberley provided a presentation on the CAEFISS information on second dose AEFIs. PHAC would like to ensure that we are able to monitor and report on AEFIs following second dose for COVID-19 vaccines: 1. AEFIs following a vaccine that is different from the first dose (mixed vaccine) 2. Severity of AEFIs following second dose (same vaccine or mixed vaccines) 3. Time interval between doses PHAC is proposing to provide the following information for all AEFIs following the second dose regardless of whether they had an AEFI of the first dose (this applies to everyone): 1. Date of previous immunization 2. Dose number 3. Vaccine trade name 4. Vaccine manufacturer This should be added to the supplementary section of the AEFI form.	Kimberley Hutchings	**ACTION:** a) PHAC will follow-up with a few questions via email to VVWG members.
8. Brighton Collaboration Update	a) [redacted] was not available this week to provide an update. This will be moved to next week's agenda	[redacted]	**ACTION:** a) This will be added to next week's agenda. [redacted] was not available this week to provide an update.
9. International and Regulatory Updates	a) Jhona provided an update on international public health agency and regulatory meetings.	Jhona Rose	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
	• HC has received all the monthly safety reports from the companies. • HC is reviewing these reports and this should be completed by early July. The outcome of these reviews will be shared with VVWG once completed. • The risk management plan for the COVID vaccine products are under review and will be shared with VVWG once completed.		
10. Roundtable - Clozapine levels following mRNA vaccines	a) PTs were asked if they have seen any cases regarding clozapine levels following mRNA vaccines. • BC has received one report of Clozapine toxicity of a [redacted] after receiving a first dose of Pfizer which was administered in February 2021. • Below is a a link to an article on "Elevated clozapine levels and toxic effects after SARS-CoV-2 vaccination" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8061735/ b) Additional agenda item: Have jurisdictions seen [redacted] at the injection site following the Pfizer vaccine? • ON is the jurisdiction that has asked this question. ON has received an unusual report of an individual where [redacted] to the injection site following a second dose of Pfizer (a physician has confirmed this and it has been reported as an AEFI). ON would like to know if any other jurisdictions have received similar reports related to this issue. This will be added to next week's agenda to discuss in further detail.	All	**ACTION:** a) No action b) The additional agenda item, have jurisdictions seen [redacted] at the injection site following the Pfizer vaccine? This will be added to next week's agenda.
11. Confirm Next Call	a) Next call: June 24, 2021 (1:30 – 3:00 EDT)	[redacted]	**ACTION:** a) No action

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Vaccine Vigilance Working Group (VVWG) Teleconference

Thursday, May 27, 2021 from 1:30 – 3:00 PM EST
Record of Decisions (RoD)

Members in Attendance:
AB: [redacted] (Provincial Co-Chair), [redacted] BC: [redacted] MB [redacted] NB [redacted] NL: [redacted] NS [redacted]
NT: [redacted] NU [redacted] ON: (MOH) [redacted] (PHO): [redacted]
PE: [redacted] QC: [redacted] SK: [redacted] YT: [redacted]

Liaison Members in Attendance:
DND: Marie-Christine Lamontagne, **IMPACT:** [redacted] **MHPD:** Jhona Rose, Battouli Said Salim, Deborah Danoff, **FNIHB:** Melanie Knight, **RCMP:** Roxanne Tauvette

Observers/Presenters in Attendance:
Amanda Shaw (Federal Co-Chair), Susanna Ogunnaike-Cooke, Helen Anyoti, Karin Johnson, Theresa Procter, Jocelyn Bougie, Andrew Atabe, Allison Yeung, Ashley Weeks, [redacted] Natalia Abraham, Erica Loughlin [redacted] Bikash Chudal, Joseline Zafack, Yvette Adonis, Helen Anyoti, Nooshin Ahmadipour, Pauline Barbeau, Wissam Hussein, Ria Sharma, Alexa Dallaire, Natalie Ward, Emmanuella Ngebunui Atanga, Carmen Leung, Melissa Hunt, Sylvie Deschambault, Megan Jackman, Mona Yazdani, Liam John Gordon, **CANVAS:** [redacted]

Regrets:
BRDD: Robert Pless, **CSC:** Samar Sarkesh

ACTION ITEMS
1. Action Item Updates
No updates to action.

Agenda Item	Description	Lead	Further Actions or Completed
1. Introduction, roll call, agenda, minutes from last meeting		Amanda Shaw	**ACTION:**

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Agenda Item	Description	Lead	Further Actions or Completed
a) Review and approval of agenda b) Review of RoD May 20, 2021	a) Agenda was approved with no additional agenda items. b) RoDs were reviewed. Amendments can be provided to Vaccine Vigilance by end of day on May 28, 2021.		a) No action b) Members can provide changes or updates to the RoDs to Vaccine Vigilance by end of day on May 28, 2021 to approve and finalize the RoD.
2. Weekly On-line COVID AEFI Report	a) Ashley/Allison provided a brief summary of the Weekly on-line COVID AEFI Report. The data provided is up to May 21, 2021.	Ashley Weeks/Allison Yeung	**ACTION:** a) The update and the embargoed report will be posted on May 28, 2021 by the end of the day.
3. CAEFISS Analysis	a) Pauline provided a presentation of the CAEFISS Weekly Report. The data provided is up to May 21, 2021. Pauline presented on menstrual events, sensorineural hearing loss, appendicitis and myocarditis. • Discussion arose for the definition of hearing loss (tinnitus, vertigo). Brighton case definition for 2020 was posted in chat. (https://brightoncollaboration.us/snhl/)	Pauline Barbeau	**ACTION:** a) The CAEFISS presentation will be posted to CNPHI after the meeting. Karin/Pauline to refine definition and to develop background rates for hearing loss.
4. Myocarditis/TTS updates	a) Natalia provided a presentation on myocarditis and TTS. • The WHO posted an alert on cases of mild myocarditis reported with COVID-19 mRNA vaccines. (https://www.who.int/news/item/26-05-2021-gacvs-myocarditis-reported-with-covid-19-mrna-vaccines)	Natalia Abraham	**ACTION:** a) Natalia's presentation will be posted to CNPHI after the meeting.
5. CANVAS Update	a) [redacted] provided an update on CANVAS. • For any questions regarding CANVAS, please contact [redacted] directly.	[redacted]	**ACTION:** a) No action

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Agenda Item	Description	Lead	Further Actions or Completed
6. Brighton Collaboration Update	a) [redacted] provided an update on Brighton Collaboration case definitions. • Myocarditis case definition – already posted on website; should be available for publication in the next two weeks. • Anaphylaxis 2.0 case definition to be revised.	[redacted]	**ACTION:** a) [redacted] to send myocarditis case definition when available.
7. Group Question - How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules? - Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine?	a) PTs provided their responses to the first group question. These have been captured in Appendix A. b) The second question has been postponed to the next VVWG meeting in the interest of time.	All	**ACTION:** a) Please see PT responses in Appendix A. Jurisdictions that were unable to provide a response will be sent an email to obtain their response. b) Add the second question "Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine?" to the next VVWG meeting.
8. Roundtable	a) No items were discussed during the roundtable discussion.	All	**ACTION:** a) No action
10. Confirm Next Call	a) Next call: June 3, 2021 (1:30 – 3:00 EDT)	Amanda Shaw	**ACTION:** a) No action

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APPENDIX A

JURISDITIONS	Question 1: How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules?	Question 2: Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine? (postponed to next meeting)
AB	[redacted]	
BC	• No link done in Panorama • Not the usual operating procedure • Would need to put in comment area • No way of determining if second dose is the same • Would need Client Immunization Record	
MB	• Able to link report • Duplicate of the Client ID • Could send Event ID	
NB	• Currently sending PDF with Client ID • Working on sending line list in excel	
NL		
NS	• Panorama could pose a challenge • Would need to work with the IT Team • Could send manually	
NT	• Not using Panorama • Can determine if a person experienced a previous AEFI • Would need to investigate how to report it	
NU	• Currently only using Moderna but small team could pull the information together manually	
ON	• Could use Client ID • Would need to investigate how to send to PHAC • Would need Client Immunization Record	
PE		
QC		

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JURISDITIONS	Question 1: How can jurisdictions report AEFIs for individuals who have received mixed vaccine schedules?	Question 2: Have jurisdictions seen cases of sensorineural hearing loss following mRNA vaccine? (postponed to next meeting)
SK	• Not currently in Panorama • Cannot send Event ID • Could put manually in brackets what first dose was • Client Immunization Record would be needed	
YT	• Panorama could pose a challenge • No link to previous doses • Could pull a report and get this information if required	

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Bradley, Kevin (HC/SC)

From: Parisien, Stéphanie (PHAC/ASPC)
Sent: 2021-01-25 12:14 PM
To: Bent, Stephen (PHAC/ASPC); Kotowski, Laura (PHAC/ASPC); Montuoro, Leonora (PHAC/ASPC); Gobeil, Simone (PHAC/ASPC); Tsamitros, Stavroula (PHAC/ASPC); Lanoix, Janelle (PHAC/ASPC); Lamarre, Catherine (PHAC/ASPC); Renee David
Subject: FW: Participation in the Vaccine Injury Support Program || Participation au Programme de soutien aux victimes d'une vaccination

Follow Up Flag: Follow up
Flag Status: Flagged

PEI confirmed their participation to VISP. Please see email below.

Stéphanie Parisien
613-277-9476

From: Arnold, Eric (PHAC/ASPC) <eric.arnold@canada.ca>
Sent: 2021-01-25 12:09 PM
To: Parisien, Stéphanie (PHAC/ASPC) <stephanie.parisien@canada.ca>
Subject: FW: Participation in the Vaccine Injury Support Program || Participation au Programme de soutien aux victimes d'une vaccination

Fyi – PEI response

From: [redacted]@gov.pe.ca>
Sent: 2021-01-15 10:09 AM
To: Robinson, Kerry (PHAC/ASPC) <kerry.robinson@canada.ca>
Cc: [redacted]@gov.pe.ca>; Mark Spidel <[redacted]@gov.pe.ca>
Subject: Re: Participation in the Vaccine Injury Support Program || Participation au Programme de soutien aux victimes d'une vaccination

Kerry,

On behalf of Deputy Minister Mark Spidel (cc'd) I am emailing you to signal PEI's intent to participate in the federally-administered VISP. Please let me know if you have any questions.

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Thanks
[redacted]

[redacted] Planning and FPT Relations
Health and Wellness
Phone: [redacted]
Email: [redacted]@gov.pe.ca

>>> "Robinson, Kerry (PHAC/ASPC)" <kerry.robinson@canada.ca> 1/8/2021 8:55 PM >>>
(le français suit)

Dear colleagues,

On December 10, 2020, the Government of Canada announced its intention to establish a pan-Canadian no-fault vaccine injury support program (VISP) in 2021.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, FPT Deputy Ministers of Health Committee on December 11, 2020, and Health Ministers Meeting on December 17, 2020.

On December 23, 2020, letters were sent from the Public Health Agency of Canada to provincial and territorial Deputy Ministers of Health asking jurisdictions to confirm whether they would participate in a federally led VISP or opt-out and establish their own programs.

Please note that responses have been requested by January 15, 2021 in order to inform program design and the solicitation process for a third party administrator.

Attached for information are answers to a series of questions that have been received from jurisdictions. Should jurisdictions have additional questions, please contact Stephen Bent, Director General of the Centre for Immunization and Respiratory Infectious Diseases at stephen.bent@canada.ca.

Best regards,

Kerry

Chers collègues,

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Le 10 décembre 2020, le gouvernement du Canada a annoncé son intention de mettre en place un programme pancanadien sans faute de soutien aux victimes d'une vaccination (PSVV) en 2021.

Les paramètres du PSVV ont été discutés au Comité consultatif spécial fédéral, provincial et territorial (FPT) sur la COVID-19 le 3 décembre 2020, au Comité FPT des sous-ministres de la Santé le 11 décembre 2020, et à la réunion des Ministres de la santé, le 17 décembre 2020.

Le 23 décembre 2020, des lettres ont été envoyées par l'Agence de la santé publique du Canada aux sous-ministres provinciaux et territoriaux de la Santé, demandant de confirmer la participation au programme dirigé par le gouvernement fédéral ou dans le cas échéant, si des programmes seraient établis au niveau provincial/territorial.

Veuillez noter que les réponses ont été demandées avant le 15 janvier 2021, pour informer l'élaboration du programme, ainsi que le processus de sollicitation pour un administrateur tiers.

Vous trouverez ci-joint pour information une série de réponses aux questions reçues des provinces et des territoires. Nous sommes à votre disposition si vous avez des questions additionnelles. Veuillez contacter Stephen Bent, Directeur Général, Centre de l'immunisation et des maladies respiratoires infectieuses à stephen.bent@canada.ca.

Meilleures salutations,

Kerry

Kerry Robinson, PhD
Associate Director General | Directrice générale associé
Intersectoral Collaboration Directorate | Direction de la collaboration intersectorielle
Strategic Policy & Planning Branch | Secteur des politiques et de la planification stratégiques
Public Health Agency of Canada | Agence de la santé publique du Canada

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Government of Saskatchewan

Ministry of Health
Deputy Minister
3rd Floor, 3475 Albert Street
Regina, Canada S4S 6X6

February 4, 2021

Kim Elmslie, Vice-President
COVID-19 Immunization Program
Public Health Agency of Canada
130 Colonnade Road
A.L. 6501H
OTTAWA ON K1A 0K9
kim.elmslie@canada.ca

Dear Kim Elmslie:

Thank you for the opportunity to participate in the No Fault Federal Vaccine Injury Support Program (VISP). Saskatchewan is interested in opting into a federal program with the understanding that:

- The program includes the provision that claimants displace their right to sue governments.
- Opting in does not bind the province to any associated costs.
- Clarity is provided regarding how the program will be implemented; through Legislation, Regulation etc.
- Clarity is provided regarding what, if any, obligations will be bestowed upon provinces and territories.

Saskatchewan recognizes the value of a national no fault VISP and looks forward to engaging in program design discussions. For further discussions, please contact [redacted]@health.gov.sk.ca.

Sincerely,

[redacted]

Max Hendricks
Deputy Minister of Health

cc: Iain Stewart, President, Public Health Agency of Canada
Dr. Stephen Lucas, Deputy Minister of Health Canada
[redacted]

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Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

PAN-CANADIAN NO-FAULT VACCINE INJURY SUPPORT PROGRAM

Presentation to the CPHO's Health Professional Forum – March 24, 2021

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Outline

Purpose

- Provide an update on implementation of the pan-Canadian no-fault Vaccine Injury Support Program (VISP)

Overview of the presentation

- Recap and Drivers
- FTP engagement
- Program design details
- Third Party Administrator
- Next Steps

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Recap – VISP Drivers

The Prime Minister announced the creation of the VISP following the First Ministers' Meeting on December 10, 2020. The program will ensure that individuals who experience a serious and permanent injury as a result of receiving a Health Canada authorized vaccine, administered in Canada, have fair and timely access to financial support.

Long-standing gap	• The VISP will strengthen Canada's immunization system. • Over 20 countries around the World have national vaccine injury support programs, including all other G7 countries.
Fairness and equity	• Without a national program, only Quebec residents have access to a no-fault compensation program.
Leadership and responsibility	• Vaccines are a public good and in the rare event of serious and permanent injury, individuals should be supported, without having to go through litigation.

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Four main areas of work…

FPT Engagement

Program Design

Third Party Selection

Next Steps – Preparing for program launch

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FPT Engagement

- All P/Ts were invited to participate in the pan-Canadian VISP, or to develop their own programs with federal financial support.
- All jurisdictions will be participating in the federally-managed VISP, with the exception of the province of Quebec, which will maintain its existing program, which has been in place for over 30 years.
- Regular updates are provided to P/Ts via a number of established governance committees – CDMH, SAC, FPT VISP Committee

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Program Design

- No fault program, applying the balance of probabilities approach in determining causality.
- Injuries must be serious and permanent – e.g. VISP would not apply to anaphylactic reactions, unless they result in long term/permanent injury to patient.
- Applies to all vaccines and immunoglobulins administered prophylactically in Canada, not just COVID-19 vaccines.
- Intent is to align with Quebec's existing program as much as possible, to ensure equivalency across Canada.
- Financial support will include: injury indemnity; income replacement; death benefits; funeral expenses, and other expenses, such as uncovered medical expenses.
- Program will be delivered via a third-party.

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Third Party Selection

- The VISP will be administered through a Contribution Agreement, with a review after five years.
- The third party will be responsible for the entirety of the compensation process, including: claims intake; causality assessment; administration of financial payments; and appeals.
- An open Call for Proposals for a 3rd party to administer the program was launched on February 10, 2021, and closed on February 24, 2021.
- Proposals were evaluated by a multi-disciplinary Review Committee.
- PHAC anticipates to select a third party and have a Contribution Agreement in place by mid-April 2021, with program launch in June 2021 (TBC).

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Next Steps – Preparing for Program Launch

- Work with the selected third party to officially launch the program.
- Continue engagement and collaboration:
  - P/Ts
  - Stakeholders and other partners
- Implement a comprehensive communications approach with partners and stakeholders to ensure awareness of VISP by Canadians and health system partners.
- Communications to be in alignment with third party communications, who will become the detailed source of information for any questions that relate to eligibility and application process.

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Yukon

Department of Health and Social Services
PO Box 2703, Whitehorse, Yukon Y1A 2C6

January 14, 2021

Kim Elmslie
Vice-President
COVID-19 Immunization Program
Public Health Agency of Canada
130 Colonnade Road
Ottawa, ON K1A 0K9

Dear Ms. Elmslie,

Thank you for the letter regarding the Vaccine Injury Support Program in December. We appreciate all the leadership and support the Public Health Agency of Canada has provided throughout the last year in regards to the COVID-19 pandemic.

The Government of Yukon does not currently have its own vaccine injury support program nor are there immediate plans to develop a program. We are grateful for the leadership the federal government is taking on this subject and we are interested in opting into the pan-Canadian Vaccine Injury Support Program (VISP).

To continue these discussions, please contact [redacted] Health Services for the Department of Health and Social Services at [redacted]@gov.yk.ca.

We look forward to working with you on this important initiative.

[redacted]
Stephen Samis
Deputy Minister
Health and Social Services
Government of Yukon

c.c.:
Dr. Stephen Lucas, Deputy Minister of Health Canada
President Iain Stewart, Public Health Agency of Canada

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Bradley, Kevin (HC/SC)

From: Parisien, Stéphanie (PHAC/ASPC)
Sent: 2021-02-02 3:32 PM
To: Kotowski, Laura (PHAC/ASPC)
Subject: FW: Participation in the Vaccine Injury Support Program

Here is the Alberta information for the PT list.

Stéphanie Parisien
613-277-9476

From: Bent, Stephen (PHAC/ASPC) <stephen.bent@canada.ca>
Sent: 2021-01-28 8:11 AM
To: Parisien, Stéphanie (PHAC/ASPC) <stephanie.parisien@canada.ca>; David, Renee (PHAC/ASPC) <renee.david@canada.ca>
Subject: FW: Participation in the Vaccine Injury Support Program

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From: Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Sent: 2021-01-28 7:55 AM
To: Bent, Stephen (PHAC/ASPC) <stephen.bent@canada.ca>
Subject: FW: Participation in the Vaccine Injury Support Program

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From: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>
Sent: 2021-01-27 7:57 PM
To: Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Subject: FW: Participation in the Vaccine Injury Support Program

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From: Lucas, Stephen (HC/SC) <stephen.lucas@canada.ca>
Sent: 2021-01-27 7:04 PM

Page: 1,502 of/de 1,581
A2021000080

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To: Stewart, Iain (PHAC/ASPC) <iain.stewart@canada.ca>; Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Subject: Fwd: Participation in the Vaccine Injury Support Program

Stephen Lucas, PhD
Deputy Minister
Health Canada

Begin forwarded message:

From: [redacted]@gov.ab.ca>
Date: January 27, 2021 at 7:01:33 PM EST
To: "Lucas, Stephen (HC/SC)" <stephen.lucas@canada.ca>
Subject: Participation in the Vaccine Injury Support Program

AR 182921

Dear Kim Elmslie:

Thank you for your correspondence in December on behalf of the Public Health Agency of Canada regarding Alberta's interest in participating in the pan-Canadian no-fault Vaccine Injury Support Program (VISP). On behalf of Alberta Health's Deputy Minister, Lorna Rosen, I am happy to respond.

I am pleased to advise you that Alberta will collaborate with the federal government and with other provinces and territories to establish criteria for this program. We recognize that assisting in the development of VISP will provide Albertans with retroactive and equitable access to financial support in the unlikely event of a serious adverse reaction after immunization from COVID-19 vaccines. We also recognize that establishment of this program may positively influence all Canadians to be immunized and support everyone's efforts on vaccine hesitancy.

I look forward to further engagements with you to discuss the program in more detail and to provide assistance and input as needed.

Please feel free to contact me for further discussions.

Sincerely,

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[redacted] Public Health and Compliance
Alberta Health

cc: Dr. Stephen Lucas, Deputy Minister of Health Canada
[redacted] Deputy Minister of Alberta Health

Classification: Protected A

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Stephen Brown
Deputy Minister of Health
Government of British Columbia
1515 Blanshard Street, 5th Floor
Victoria, British Columbia V8W 3C8

Dear Mr. Brown:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, and at the FPT Deputy Ministers of Health Committee on December 11, 2020.

The VISP will be federally funded and provide coverage for all uninsured costs resulting from serious permanent injuries sustained following administration of any Health Canada-approved vaccines, including COVID-19 vaccines, as of December 8, 2020. The expectation is that a third party administrator, selected through a competitive solicitation process, will manage the VISP; however, if a suitable third party cannot be identified, the Public Health Agency of Canada will administer the program. Our goal is to have a third party administrator in place and able to accept claims for compensation by June 1, 2021. The initial agreement with a third party administrator will be for five years, with a review of the program at that time.

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Recognizing that immunization is an area of shared responsibility while also ensuring that every Canadian has access to financial support, provinces and territories have the flexibility to opt out of the pan-Canadian VISP should they wish to develop and implement an equivalent program within their own jurisdiction. In such cases, federal funding would be available to support the provincial or territorial program, provided that it meets federal objectives and criteria.

A provincial or territorial program would need to encompass certain parameters, including:

- Program to be established in 2021 with coverage retroactive to December 8, 2020;
- Coverage applying to all Health Canada approved vaccines;
- Program design to be "no-fault";
- Financial support to cover serious permanent injury;
- Applicants to have a three year window to apply for financial support; and
- Program to include an appeal mechanism for unsuccessful claimants.

In order to proceed with the next steps of implementing the pan-Canadian VISP, we are asking that you advise us whether your jurisdiction intends to be covered by the federal program or whether your jurisdiction wishes to implement its own specific program.

We kindly ask that you advise us of your intention by January 15, 2021, to ensure sufficient time is available for bilateral engagements with jurisdictions, particularly with those who choose to opt out of the pan-Canadian VISP, to confirm program and funding parameters.

Please send your response and provide a point of contact for further discussions to Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca.

Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada | Agence de la santé publique du Canada

Ottawa, Ontario K1A 0K9 | Ottawa (Ontario) K1A 0K9

DEC 2 3 2020

Ms. Karen Stone
Deputy Minister of Health & Community Services
Government of Newfoundland & Labrador
P.O. Box 8700
Confederation Building, West Block
St. John's, Newfoundland Labrador A1B 4J6

Dear Ms. Stone:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, and at the FPT Deputy Ministers of Health Committee on December 11, 2020.

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In order to proceed with the next steps of implementing the pan-Canadian VISP, we are asking that you advise us whether your jurisdiction intends to be covered by the federal program or whether your jurisdiction wishes to implement its own specific program.

We kindly ask that you advise us of your intention by January 15, 2021, to ensure sufficient time is available for bilateral engagements with jurisdictions, particularly with those who choose to opt out of the pan-Canadian VISP, to confirm program and funding parameters.

Please send your response and provide a point of contact for further discussions to Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca.

Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Ms. Ruby Brown
Deputy Minister of Health
Government of Nunavut
PO Box 1000 Stn 1000
Iqaluit, Nunavut X0A 0H0

Dear Ms. Brown:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Bruce Cooper
Deputy Minister of Health and Social Services
Government of the Northwest Territories
PO Box 1320
New Government Building, 7th Floor
5015 – 49th Street
Yellowknife, Northwest Territories X1A 2L9

Dear Mr. Cooper:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Please send your response and provide a point of contact for further discussions to Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca.

Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Stephen Samis
Deputy Minister of Health and Social Services
Government of the Yukon, H-1
P.O. Box 2703
Whitehorse, Yukon Y1A 2C6

Dear Mr. Samis:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Ms. Lorna Rosen
Deputy Minister of Health
Office of the Deputy Minister Health
22nd fl ATB Place NT
10025 Jasper Avenue
Edmonton, Alberta T5J 1S6

Dear Ms. Rosen:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Max Hendricks
Deputy Minister of Health
Province of Saskatchewan
T.C. Douglas Building
3475 Albert Street, 3rd Floor
Regina, Saskatchewan S4S 6X6

Dear Mr. Hendricks:

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Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Ms. Karen Herd
Deputy Minister of Health, Seniors and Active Living
Province of Manitoba
Legislative Building, Room 310
450 Broadway
Winnipeg, Manitoba R3C 0V8

Dear Ms. Herd:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Sincerely,

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c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Ms. Helen Angus
Deputy Minister
Ministry of Health and Long-Term Care
777 Bay Street, Floor 5
Toronto, Ontario M5G 2E5

Dear Ms. Angus:

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Gérald Richard
Deputy Minister of Health
Province of New Brunswick
PO Box 5100
520 King Street, 5th Floor
Fredericton, New Brunswick E3B 5G8

Dear Mr. Richard:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

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Sincerely,

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c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Agence de la santé publique du Canada
Ottawa (Ontario)
K1A 0K9

Public Health Agency of Canada
Ottawa, Ontario
K1A 0K9

DEC 2 3 2020

Monsieur Gérald Richard
Sous-ministre de la Santé
Province du Nouveau-Brunswick
Place HSBC, C. P. 5100
Fredericton, Nouveau-Brunswick E3B 5G8

Monsieur,

Le 10 décembre 2020, le gouvernement du Canada a annoncé son intention de mettre en œuvre un programme pancanadien de soutien aux victimes d'une vaccination (PSVV) sans égard à la faute. Ce programme permettra de renforcer le système d'immunisation du Canada en comblant une lacune de longue date et démontrera que le Canada, comme d'autres pays, reconnaît que, dans les rares cas de blessures graves et permanentes subies à la suite d'une vaccination, il est juste que les victimes reçoivent le soutien dont ils ont besoin. Le PSVV aidera également le Canada à demeurer concurrentiel dans l'accès à de nouveaux vaccins au fur et à mesure qu'ils deviennent disponibles, et permettra au Canada de s'harmoniser avec les autres pays du G7, qui sont tous déjà dotés de programmes nationaux à cet égard.

Les paramètres du PSVV pancanadien ont fait l'objet de discussions lors de la réunion du Comité consultatif spécial fédéral, provincial et territorial (FPT) sur la COVID-19 le 3 décembre 2020 et lors de la réunion du Comité des sous-ministres FPT de la Santé le 11 décembre 2020.

Le PSVV sera financé par le gouvernement fédéral et offrira une couverture pour les coûts non assurés engendrés par des blessures graves et permanentes subies à la suite de l'administration de tout vaccin approuvé par Santé Canada, y compris les vaccins contre la COVID-19, à compter du 8 décembre 2020. Il est attendu qu'un administrateur indépendant, sélectionné à la suite d'un processus de demandes de soumissions concurrentiel, gérera le PSVV. Cependant, s'il est impossible de trouver un administrateur indépendant compétent, l'Agence de la santé publique du Canada administrera le programme. Notre objectif consiste à mettre en place

.../2

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un administrateur indépendant qui est à même de recevoir des demandes d'indemnisation à compter du 1er juin 2021. L'entente initiale avec un administrateur indépendant sera d'une durée de cinq ans, à la suite de laquelle un examen du programme sera effectué.

Nous reconnaissons que la vaccination est un champ de compétence partagée et désirons aussi garantir l'accès, pour tous les Canadiens, à un soutien financier, c'est pourquoi nous donnons aux provinces et aux territoires la possibilité de se retirer du PSVV pancanadien s'ils souhaitent élaborer et mettre en œuvre un programme équivalent relevant de leur propre administration. Dans de tels cas, un financement fédéral serait offert pour appuyer le programme provincial ou territorial, pourvu que celui-ci respecte les objectifs et les critères fédéraux.

Il faudrait qu'un tel programme provincial ou territorial comporte certains paramètres, notamment :

- Le programme doit être mis sur pied en 2021 et être doté d'une couverture rétroactive au 8 décembre 2020.
- La couverture doit s'appliquer à tous les vaccins approuvés par Santé Canada.
- Le programme doit être conçu de façon à être « sans égard à la faute ».
- Le soutien financier doit couvrir une blessure grave et permanente.
- Les demandeurs doivent disposer d'une période de trois ans pour présenter une demande de soutien financier.
- Le programme doit prévoir un mécanisme d'appel pour les personnes dont la demande a été rejetée.

Afin de passer aux prochaines étapes de la mise en œuvre du PSVV pancanadien, nous vous prions de nous indiquer si votre administration compte être couverte par le programme fédéral ou si elle envisage de mettre en place son propre programme.

Nous vous saurions gré de nous faire part de votre intention au plus tard le 15 janvier 2021 afin que nous disposions de suffisamment de temps pour tenir des entretiens bilatéraux avec les administrations, en particulier avec celles qui décident de ne pas adhérer au PSVV pancanadien, en vue de confirmer les paramètres du programme et du financement.

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Veuillez faire parvenir votre réponse et fournir un point de contact pour poursuivre les discussions à Kim Elmslie, vice-présidente, programme d'immunisation contre la COVID-19, à l'adresse kim.elmslie@canada.ca.

Cordialement,

Iain Stewart
Président

c. c. : Dr Stephen Lucas, sous-ministre de Santé Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Dr. Kevin Orrell
Deputy Minister of Health & Wellness
17th Floor, Barrington Tower
1894 Barrington Street
P.O. Box 488
Halifax, Nova Scotia B3J 2R8

Dear Dr. Orrell:

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Sincerely,

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President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Public Health Agency of Canada
Agence de la santé publique du Canada

Ottawa, Ontario
K1A 0K9

Ottawa (Ontario)
K1A 0K9

DEC 2 3 2020

Mr. Mark Spidel
Deputy Minister of Health and Wellness
Province of Prince Edward Island
105 Rochford Street
4th Floor Shaw North
Charlottetown, Prince Edward Island C1A 7N8

Dear Mr. Spidel:

On December 10, 2020, the Government of Canada announced its intention to implement a pan-Canadian no-fault vaccine injury support program (VISP). This program will strengthen Canada's immunization landscape by addressing a longstanding gap and will demonstrate that Canada, like other countries, recognizes that in the rare instances of serious permanent injury due to vaccination, it is right that individuals receive the support they need. A VISP will also help Canada remain competitive in accessing new vaccines as they become available, and will align Canada with other G7 countries, all of which have national programs in place.

The parameters of the pan-Canadian VISP have been discussed at the federal, provincial and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, and at the FPT Deputy Ministers of Health Committee on December 11, 2020.

The VISP will be federally funded and provide coverage for all uninsured costs resulting from serious permanent injuries sustained following administration of any Health Canada-approved vaccines, including COVID-19 vaccines, as of December 8, 2020. The expectation is that a third party administrator, selected through a competitive solicitation process, will manage the VISP; however, if a suitable third party cannot be identified, the Public Health Agency of Canada will administer the program. Our goal is to have a third party administrator in place and able to accept claims for compensation by June 1, 2021. The initial agreement with a third party administrator will be for five years, with a review of the program at that time.

.../2

Canada

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Recognizing that immunization is an area of shared responsibility while also ensuring that every Canadian has access to financial support, provinces and territories have the flexibility to opt out of the pan-Canadian VISP should they wish to develop and implement an equivalent program within their own jurisdiction. In such cases, federal funding would be available to support the provincial or territorial program, provided that it meets federal objectives and criteria.

A provincial or territorial program would need to encompass certain parameters, including:

- Program to be established in 2021 with coverage retroactive to December 8, 2020;
- Coverage applying to all Health Canada approved vaccines;
- Program design to be "no-fault";
- Financial support to cover serious permanent injury;
- Applicants to have a three year window to apply for financial support; and
- Program to include an appeal mechanism for unsuccessful claimants.

In order to proceed with the next steps of implementing the pan-Canadian VISP, we are asking that you advise us whether your jurisdiction intends to be covered by the federal program or whether your jurisdiction wishes to implement its own specific program.

We kindly ask that you advise us of your intention by January 15, 2021, to ensure sufficient time is available for bilateral engagements with jurisdictions, particularly with those who choose to opt out of the pan-Canadian VISP, to confirm program and funding parameters.

Please send your response and provide a point of contact for further discussions to Kim Elmslie, Vice-President, COVID-19 Immunization Program, at kim.elmslie@canada.ca.

Sincerely,

Iain Stewart
President

c.c.: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Agence de la santé publique du Canada
Ottawa (Ontario)
K1A 0K9

Public Health Agency of Canada
Ottawa, Ontario
K1A 0K9

DEC 2 3 2020

Madame Dominique Savoie
Sous-ministre de la Santé et des Services Sociaux
Ministère de la Santé et des Services sociaux
Édifice Catherine-de-Longpré
1075, chemin Sainte-Foy, 14e étage
Québec (Québec) G1S 2M1

Madame,

Le 10 décembre 2020, le gouvernement du Canada a annoncé son intention de mettre en œuvre un programme pancanadien de soutien aux victimes d'une vaccination (PSVV) sans égard à la faute. Ce programme permettra de renforcer le système d'immunisation du Canada en comblant une lacune de longue date et démontrera que le Canada, comme d'autres pays, reconnaît que, dans les rares cas de blessures graves et permanentes subies à la suite d'une vaccination, il est juste que les victimes reçoivent le soutien dont ils ont besoin. Le PSVV aidera également le Canada à demeurer concurrentiel dans l'accès à de nouveaux vaccins au fur et à mesure qu'ils deviennent disponibles, et permettra au Canada de s'harmoniser avec les autres pays du G7, qui sont tous déjà dotés de programmes nationaux à cet égard.

Les paramètres du PSVV pancanadien ont fait l'objet de discussions lors de la réunion du Comité consultatif spécial fédéral, provincial et territorial (FPT) sur la COVID-19 le 3 décembre 2020 et lors de la réunion du Comité des sous-ministres FPT de la Santé le 11 décembre 2020.

Compte tenu du leadership de longue date du Québec à ce sujet, qui est la seule province au Canada à avoir mis en place avec efficacité un programme d'indemnisation des victimes d'une vaccination sans égard à la faute, nous espérons tirer parti de votre expertise et apprendre de votre expérience en ce qui concerne la gestion et l'administration de votre programme.

Le PSVV sera financé par le gouvernement fédéral et offrira une couverture pour les coûts non assurés engendrés par des blessures graves et permanentes subies à la suite de l'administration de tout vaccin approuvé par Santé Canada, y compris les vaccins contre la COVID-19, à compter du

.../2

Canada

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8 décembre 2020. Les provinces et les territoires, dont le Québec, auront la possibilité de se retirer du programme pancanadien et de mettre en place ou de maintenir un programme équivalent. Dans de tels cas, un financement fédéral serait disponible pour soutenir le programme provincial ou territorial par l'entremise d'un accord de contribution.

Il faudrait qu'un tel programme provincial ou territorial comporte certains paramètres, notamment :

- Le programme doit être mis sur pied en 2021 et être doté d'une couverture rétroactive au 8 décembre 2020.
- La couverture doit s'appliquer à tous les vaccins approuvés par Santé Canada.
- Le programme doit être conçu de façon à être « sans égard à la faute ».
- Le soutien financier doit couvrir une blessure grave et permanente.
- Les demandeurs doivent disposer d'une période de trois ans pour présenter une demande de soutien financier.
- Le programme doit prévoir un mécanisme d'appel pour les personnes dont la demande a été rejetée.

Tel que mentionné lors de l'appel entre le Dr Howard Njoo et le Dr Horacio Arruda le 3 décembre 2020, le Québec maintiendra son programme actuel. Par conséquent, nous aimerions organiser des discussions pour confirmer les détails relatifs aux ententes de financement à venir.

Nous vous saurions gré de confirmer votre intention par écrit au plus tard le 15 janvier 2021 et de fournir un point de contact pour poursuivre les discussions afin de garantir la rapidité de la mise en œuvre du programme et du transfert de fonds.

Veuillez faire parvenir votre réponse et adresser toutes vos questions à Kim Elmslie, vice-présidente, programme d'immunisation contre la COVID-19, à l'adresse kim.elmslie@canada.ca.

Cordialement,

Iain Stewart
Président

c. c. : Dr Stephen Lucas, sous-ministre, Santé Canada.

ATIA - 19(1)

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BRITISH COLUMBIA

January 13, 2021

1184859

Via email: kim.elmslie@canada.ca

Mr. Iain Stewart, President
Ms. Kim Elmslie, Vice-President
COVID-19 Immunization Program
Public Health Agency of Canada
130 Colonnade Road
A.L. 6501H
Ottawa ON K1A 0K9

Dear Mr. Stewart and Ms. Elmslie:

Thank you for your letter of December 23, 2020, seeking confirmation of whether it is British Columbia's intention to be covered by the pan-Canadian no-fault vaccine injury support program (VISP) or to implement a separate VISP specific to British Columbia.

I can confirm that British Columbia will be participating in the federal VISP program as discussed at the federal, provincial, and territorial (FPT) Special Advisory Committee on COVID-19 on December 3, 2020, and at the FPT Deputy Ministers of Health Committee on December 11, 2020. The point of contact for British Columbia is Lorie Hrycuik, Executive Lead, Population and Public Health Division. Ms. Hrycuik may be contacted at (778) 974-3766 or via email at lorie.hrycuik@gov.bc.ca.

I appreciate the opportunity to respond.

Sincerely,

[redacted]

Stephen Brown
Deputy Minister

Ministry of Health Office of the Deputy Minister PO Box 9639 STN PROV GOVT Victoria BC V8W 9P1

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Manitoba
Health, Seniors and Active Living
Deputy Minister
Room 310 Legislative Building, 450 Broadway
Winnipeg, Manitoba Canada R3C 0V8

DEC 3 0 2020

Iain Stewart
President
Public Health Agency of Canada
E-mail: iain.stewart@canada.ca

Dear Mr. Stewart:

Thank you for your letter of December 23, 2020 outlining the Government of Canada's intent to establish and implement a pan-Canadian no-fault vaccine injury support program (VISP). My response letter is to confirm that Manitoba intends to be covered by the Federal VISP rather than implementing a Manitoba-specific program. Manitoba's point of contact for further discussions will be [redacted] Population Health (PH), [redacted]

Sincerely,

[redacted]

Karen Herd, CA

c. Kim Elmslie, Vice President COVID 19 Immunization Program
Dr. Stephen Lucas, Deputy Minister of Health Canada
[redacted] PH, Manitoba Health, Seniors and Active Living

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New Nouveau Brunswick
CANADA

January 21, 2021

Ms. Kim Elmslie, Vice-President
Kim.elmslie@canada.ca

Dear Ms. Elmslie :

This is in response to a letter from Mr. Iain Stewart, dated December 23, 2021, regarding New Brunswick's proposed participation in a pan-Canadian no-fault vaccine injury support program.

New Brunswick's Department of Health is supportive of the pan-Canadian no-fault vaccine injury support program (VISP) offered by the Federal Government. The Department looks forward to participating in discussions over the coming months to outline program details such as the parameters for participation. This dialogue, along with any additional information on the pan-Canadian no-fault VISP, will aid in consultations within the government of New Brunswick.

Please be aware that moving forward the point of contact for New Brunswick's Department of Health will be [redacted] Corporate Services and Francophone Affairs. He can be reached at [redacted]@gnb.ca.

Thank you for sharing this information with the government of New Brunswick.

Sincerely

[redacted]

Gérald Richard
Deputy Minister

cc: Mr. Iain Stewart, President, Public Health Agency of Canada
Dr. Stephen Lucas, Deputy Minister, Health Canada
[redacted] Department of Health

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New Nouveau Brunswick
CANADA

Le 21 janvier 2021

Madame Kim Elmslie, vice-présidente
Kim.elmslie@canada.ca

Madame,

La présente fait suite à une lettre envoyée par M. Iain Stewart le 23 décembre 2020 concernant la participation proposée du Nouveau-Brunswick à un programme pancanadien de soutien aux victimes d'une vaccination sans égard à la faute.

Le ministère de la Santé du Nouveau-Brunswick appuie le programme pancanadien de soutien aux victimes d'une vaccination sans égard à la faute offert par le gouvernement fédéral. Le Ministère a hâte de participer aux discussions des prochains mois afin de passer en revue les détails du programme, notamment les paramètres de participation. Ce dialogue, ainsi que tout renseignement supplémentaire sur le programme pancanadien de soutien aux victimes d'une vaccination sans égard à la faute, sera utile en vue des consultations au sein du gouvernement du Nouveau-Brunswick.

Sachez qu'à partir de maintenant la personne-ressource du ministère de la Santé du Nouveau-Brunswick sera [redacted] Services ministériels et des Affaires francophones. Il peut être joint au [redacted]@gnb.ca.

Vous remerciant d'avoir partagé cette information avec le gouvernement du Nouveau-Brunswick, je vous prie d'agréer, Madame, l'expression de mes sentiments les meilleurs.

Le sous-ministre,

[redacted]

Gerald Richard

c. c.: M. Iain Stewart, président, Agence de la santé publique du Canada
Dr Stephen Lucas, sous-ministre, Santé Canada
[redacted] ministère de la Santé

Health/Santé
P.O. Box/C.P. 5100 Fredericton New Brunswick/Nouveau-Brunswick E3B 5G8 Canada

www.gnb.ca

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Newfoundland Labrador

Government of Newfoundland and Labrador
Department of Health and Community Services
Office of the Deputy Minister

COR-2021-137074/01

January 15, 2021

Ms. Kim Elmslie
Vice-President
COVID-19 Immunization Program
Public Health Agency of Canada
kim.elmslie@canada.ca

Dear Ms. Elmslie:

I am writing in response to correspondence dated December 23, 2020, from Mr. Iain Stewart, President of the Public Health Agency of Canada (PHAC), regarding the pan-Canadian no-fault Vaccine Injury Support Program (VISP). We have conducted some internal analysis and Newfoundland and Labrador is supportive of participating in the pan-Canadian VISP program.

We look forward to participating in further discussions with the Public Health Agency of Canada and obtaining more information on the federal program and provincial-territorial responsibilities and requirements.

In this regard, the point of contact for Newfoundland and Labrador will be [redacted] Regional Services. He can be contacted by email at [redacted]@gov.nl.ca and by phone at [redacted]

Sincerely,

[redacted]

Karen Stone
Deputy Minister

cc: [redacted] Regional Services

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NOVA SCOTIA
Health and Wellness
Office of the Deputy Minister

PO Box 488
Halifax, Nova Scotia
Canada B3J 2R8

902 424-7570 t
902-424-4570 f
novascotia.ca/dhw

January 12, 2021

Kimberly Elmslie
Vice-President
COVID-19 Immunization Program
Public Health Agency of Canada

Dear Ms. Elmslie:

I am writing in response to President Iain Stewart's letter of December 23, 2020, which provided formal notice of the Government of Canada's intent to establish the Pan-Canadian no-fault Vaccine Injury Support Program (VISP).

This letter is to advise you that Nova Scotia supports the establishment of VISP. This program will strengthen Canada's immunization landscape and recognizes that individuals who sustain serious permanent injury due to vaccination ought to receive the support they need. VISP will also align Canada with other G7 countries, all of which have national vaccine injury programs in place.

Nova Scotia intends to be covered by the federal program; Nova Scotia does not intend to implement its own specific program.

Dr. Robert Strang, Nova Scotia's Chief Medical Officer of Health, will be Nova Scotia's point of contact for further discussions. He can be reached at: [redacted]@novascotia.ca or [redacted]

Yours truly,

[redacted]

Kevin G.S. Orrell M.D., FRCSC, MBA(CED)
Deputy Minister of Health and Wellness

c [redacted] Chief Medical Officer of Health

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Government of Northwest Territories / Gouvernement des Territoires du Nord-Ouest

January 11, 2021

Ms. Kim Elmslie
Vice-President
COVID-19 Immunization Program
PUBLIC HEALTH AGENCY OF CANADA
OTTAWA ON K1A 0K9

SENT VIA EMAIL: kim.elmslie@canada.ca

Dear Ms. Elmslie:

Vaccine Injury Support Program

I am writing in response to the letter received from Mr. Iain Stewart respecting the Government of Canada's intention to implement a pan-Canadian no-fault vaccine injury support program (VISP).

The Northwest Territories intends to be covered by the federal program and does not wish to implement our own specific program at this time.

Further discussions on the VISP can be directed to the following contact for the Northwest Territories:

[redacted] Legislation and Communications
Department of Health and Social Services
Government of the Northwest Territories
[redacted]@gov.nt.ca

We look forward to more information on the details of this program, and the implications for the Northwest Territories, prior to providing formal approval.

Sincerely

[redacted]

Bruce Cooper
Deputy Minister
Health and Social Services

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Bradley, Kevin (HC/SC)

From: Parisien, Stéphanie (PHAC/ASPC)
Sent: 2021-01-11 10:00 AM
To: Lamarre, Catherine (PHAC/ASPC); Gobeil, Simone (PHAC/ASPC); Kotowski, Laura (PHAC/ASPC); Montuoro, Leonora (PHAC/ASPC); Tsamitros, Stavroula (PHAC/ASPC); Lanoix, Janelle (PHAC/ASPC)
Cc: Arnold, Eric (PHAC/ASPC); Robinson, Kerry (PHAC/ASPC)
Subject: FW: Nunavut's participation - VISP

One more response.
Laura, can you add this name to the list of contacts?

Merci,

Stéphanie Parisien
613-277-9476

From: Bent, Stephen (PHAC/ASPC) <stephen.bent@canada.ca>
Sent: 2021-01-11 9:54 AM
To: Parisien, Stéphanie (PHAC/ASPC) <stephanie.parisien@canada.ca>; Renee David <Renee.David@tpsgc-pwgsc.gc.ca>
Subject: FW: Nunavut's participation - VISP

From: Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Sent: 2021-01-11 9:27 AM
To: Bent, Stephen (PHAC/ASPC) <stephen.bent@canada.ca>
Subject: FW: Nunavut's participation - VISP

From: [redacted]@GOV.NU.CA>
Sent: 2021-01-11 9:15 AM
To: Elmslie, Kim (PHAC/ASPC) <kim.elmslie@canada.ca>
Cc: Brown, Ruby <[redacted]@GOV.NU.CA>; [redacted]@GOV.NU.CA>; [redacted]@GOV.NU.CA>
Subject: Nunavut's participation - VISP

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Ullaakkut,

This message is sent on behalf of DM Ruby Brown.

Thank you for the information to date on the VISP. The Government of Nunavut intends to use the federal program. If further follow up is required please contact Linnea Ingebrigtson, Director Policy and Planning, at [redacted]@gov.nu.ca.

Nakurmiik,

[redacted]

[redacted]

[redacted] ᐊᑐᕐᓇᓂᖅ ᐱᓇᓱᒋᔭᐅᓂᖅ
Policy and Planning
Aulapkaiyi, Atugakhanik Upalungaiyaliqiyunitlu
Directrice, Politique et Planification

ᐃᓄᓐᓂᐅᑦᑎᐊᖅᑐᑦ ᐱᖓᓱᐃᓕᓴᕐᓂᖅ
Department of Health
Munaqhiliqiyitkut
Ministère de la Santé

P.O. Box 1000, Stn. 1000
Iqaluit, Nunavut X0A 0H0

C. P. 1000, succursale 1000
Iqaluit (Nunavut) X0A 0H0

[redacted]@gov.nu.ca

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Ministry of Health

Office of the Deputy Minister

777 Bay Street, 5th Floor
Toronto ON M7A 1N3
Tel.: 416 327-4300
Fax: 416 326-1570

Ministère de la Santé

Bureau du sous-ministre

777, rue Bay, 5e étage
Toronto ON M7A 1N3
Tél. : 416 327-4300
Téléc. : 416 326-1570

Ontario

January 15, 2021

Mr. Iain Stewart
President, Public Health Agency of Canada
130 Colonnade Road, Room 145B
Postal Locator: 6501-B
Ottawa, ON K1A 0K9

Dear Mr. Stewart:

I am writing to you in response to your December 23, 2020 correspondence related to the federal government's proposed pan-Canadian no-fault vaccine injury support program (VISP).

I would like to take this opportunity to confirm Ontario's decision to opt-in to the proposed VISP. A federally funded VISP will help bolster immunization programs across the country, while also providing general uniformity in supports available for individuals who may experience serious permanent injury due to the administration of approved vaccinations.

We look forward to receiving additional information from your officials on program design and planned engagement with participating jurisdictions. We are also interested in learning more about planning for public communications related to the VISP. Developing a robust communications plan, in collaboration with participating jurisdictions, will be important to maintain the public's trust and help counter misinformation and vaccine hesitancy.

Ontario's point of contact for further discussions related to the VISP is:

[redacted] Pandemic Response and Recovery, Ministry of Health
Email: [redacted]
Phone

In closing, I would like to thank you and your officials for your ongoing collaboration, as well as for the work completed to date to commence this important public health program.

Sincerely,

[redacted]

Helen Angus
Deputy Minister

cc: Dr. Stephen Lucas, Deputy Minister of Health Canada

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Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada

Canada

No-Fault Vaccine Injury Compensation Program

Planning Considerations
August 17, Version 9

SECRET

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Issue

- Whether the Government of Canada should take the lead at this time to:

  a) establish a national no-fault vaccine injury compensation (VIC) program to support COVID-19 vaccine deployment

  b) if yes:
     - what should be the core elements of this program?

     - whether/how to use the new program to incent PTs to enhance post-market vaccine safety monitoring?

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Background

- As with all vaccines, a small number of Canadians will experience an adverse event following immunization (AEFI) related to a new COVID-19 vaccine, ranging from mild (e.g. pain at the injection site, fever) to more severe (e.g. anaphylaxis and in very rare instances death)

- The traditional core argument for no-fault VIC hinges on the ethical principal of reciprocity given the societal benefits of vaccination

- Despite broad F/P/T support for the underlying principles of a VIC since it was first debated in the 1980s, consensus on whether/how to establish a "national " system has proven elusive:
  - who should fund/administer the system?
  - scope of coverage: pandemic vaccine or all vaccines?
  - compensation protection for vaccines administered consistent with National Advisory Committee on Immunization (NACI) guidance or as guidance has been interpreted by P/Ts, professional bodies or clinicians?
  - how to determine equitable compensation limits across jurisdictions?
  - what baseline post-market vaccine safety monitoring system must P/Ts have in place to participate (and who determines compliance)?

- Canada is the only G-7 country without a VIC; Quebec established a VIC in 1988

ATIA - 21(1)(b)

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Why has VIC emerged as an issue at this time?

- Results from a convergence of factors:
  - growing risk of pandemics (due to global travel, mobility, urbanization and higher-risk forms of agriculture)
  - concomitant rise in demand for rapidly developed/tested novel pandemic vaccines that may expose manufacturers (especially innovative ones) to levels of risk and uncertainty they are unable to shoulder
  - recognition indemnifying manufacturers/health agencies from litigation is an inadequate remedy for vaccine injuries
- COVID-19 has added new urgency to the discussion for Canada
  - [redacted]
  - WHO has proposed integrating a pandemic injury compensation scheme into its global-vaccine development facility in which Canada has formally expressed an interest in participating
  - GOC may be pay up-front for securing COVID-19 vaccine and indemnifying suppliers and in doing so, will assume a higher share of potential liability for vaccine injury than is the norm (where PTs pay and indemnify)

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Some lessons from other Jurisdictions*

- Comparative data on serious vaccine injury from a 2011 CIHR-funded study of countries with VIC suggests that:
  - despite divergent approaches to compensation, serious injuries claims are typically less than 1-2 per million people vaccinated
  - less than half of serious claims justified compensation
  - while under-filing of injury claims and non-compensation of claims due to lack of scientific merit may be an issue, the case load across jurisdictions studied suggests VIC regimes are processing similar numbers of claims
- The 2011 study is being updated and preliminary results are that:
  - the trend since most VIC programs were created is towards a decline in the number of claims and awards
  - the existence of no-fault VIC has resulted in the development of more integrated systems to detect adverse events and new agencies to review and study association between vaccination and adverse events
  - the creation of VIC programs can lead to a surge in claims, but that these events are usually short-lived and have not resulted in a sustained or unbearable burden on new VIC systems

***See Annex 1 for lessons from other jurisdictions**

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Quebec and United States: alternative approaches

Quebec's Experience: comprehensive program

- **Since 1988,** Quebec's VIC has reviewed **284 cases** (8.5 annually). Of these: **53 claims accepted** and **44 were not pursued**. In total, **over 32 years,** successful claimants have received a total of **$6.5 million** ($200k annually).

- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec has an Administrative Tribunal that reviews the cases; if the decision is in favour of the applicant, the government has a third party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).

United States' Experience: VIC for childhood vaccines + one-time VIC for H1N1-pandemic vaccine

- United States has an established VIC program financed by an excise tax on vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children.

- In 2009, the United States used an emergency program (*Countermeasures Injury Compensation Program)* to implement a VIC scheme for H1N1 pandemic vaccine recipients, providing similar protection as its ongoing program

- US has a system that resembles civil litigation, with the government acting as the defendant and the injured party as the plaintiff in each case. Both parties are represented by lawyers, produce expert witnesses, and argue their cases before specialized judges.

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Potential Elements for a COVID-19 VIC Program

- **Principle Aim**:
  - Fairly compensate those who experience a COVID-19 vaccine AEFI when vaccine administered consistent with NACI guidance
- **Administration:**
  - Administered by an arms-length agency, independent from branches of government responsible for vaccine regulation/promotion
- **Coverage**:
  - AEFI must result in a measurable *uninsured* damages or costs (in case of death, paid out similar to accidental death benefit)
- **Statue Limitations**:
  - Reasonable statute of limitations for filing claims, with sufficient documentation to substantiate injury
- **Adjudication for Claimants (2 streams):**
  - Table of Injury Review: a predetermined table will identify anticipated COVID-19 AEFIs (extrapolated from historical vaccine AEFI levels); if claimant meets criteria, compensation is granted
  - Individual Case Review (Tribunal): if claimant's injury not covered by the Table, a 3-person expert panel will assess the claim using a defined causality test (1 neutral member, 1 for claimant and 1 for the relevant jurisdiction)
- **Compensation:**
  - Degree of disability and compensation will be determined by a body with expertise adjudicating disability claims

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Planning Considerations: Is this the right time to establish a VIC?

- **Rationale for establishing a VIC for COVID-19 vaccine deployment:**
  - addresses the concerns of one (or more) potential COVID-19 vaccine suppliers
  - brings Canada into line with other countries
  - chance to leverage limited window-of-opportunity to achieve transformational change in post-market vaccine safety monitoring
  - implementation costs marginal relative to potential benefits
- **Rationale for not proceeding at this time:**

[redacted]

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Planning considerations: A national VIC vs incenting PTs to create regimes?

- **Rationale for a national VIC regime (with PT opt-in):**
  - absent GoC leadership, equitable pan-Canadian VIC coverage unlikely
  - national system can be established quickly at a relatively low-cost (but unclear if a new VIC can be ready for COVID-19 vaccine deployment)
  - a national VIC is a natural extension of post-COVID-19 expanded federal public health role (i.e. if GoC buys pandemic vaccines, indemnifies suppliers, VIC is logical next step…)
  - P/T opt-in requirements can incent changes in vaccine safety monitoring
- **Rationale for PT-regimes:**
  - P/Ts (not the GoC) are the primary decision-makers re- vaccine use and administration (i.e. should a national VIC program offer compensation if PTs have not followed NACI guidance?)
  - P/Ts can better tailor VIC to local realities, existing P/T support programs for disabilities (e.g. use P/T Workman Compensation Boards or No-Fault Auto Insurance Boards to assess disability/fix compensation)
  - PTs can implement VIC at their own pace, rather than scramble in the midst of an outbreak

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Planning considerations: Limit VIC coverage to COVID-19 vaccine or extend to all HC-approved vaccines (administered consistent with NACI guidance)?

- **Rationale for limiting VIC to COVID-19 vaccine:**
  - addresses immediate concerns of potential COVID-19 suppliers
  - more limited, less costly and achievable program that can be pitched as a "pilot" for an expanded VIC
  - acknowledges that a new vaccine developed and approved quickly in response to a significant novel pathogen outbreak or pandemic, may be based on more limited safety data from clinical trials and usage
  - reaffirms federal leadership and a "whole-of-Canada" commitment in responding to public health emergencies
- **Rationale for extending VIC to all vaccines:**
  - reciprocity principle applies for all vaccines, not just COVID-19 vaccine
  - broader coverage with opt-in linked to adherence to NACI guidance may incent progress towards a single national vaccine schedule
  - can be pitched as bringing Canada into line with international community and helps ensures a consistent and equitable pan-Canadian approach to AEFI compensation
  - infrastructure/processes for a comprehensive VIC are similar

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Next Steps

[redacted]

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Annex 1: Lessons from other Jurisdictions

How are no-fault programmes typically run?

- Worldwide, most no-fault programmes are government-run and national in scope. They generally fall under the administration of state ministries related to health and social welfare or labour (UK) or there is federal/national legislation that governs an arms-length overseeing agency (NZ). Only in Sweden is the no-fault programme covered under a private drug insurance scheme.

What vaccines are usually covered?

- Most no-fault compensation programmes were implemented in the 1970s and 1980s when vaccine programmes targeted infants and school-aged children. Thus, some programmes restrict eligibility for compensation to government recommended vaccinations given to infants and children. In some instances, vaccinations required by state mandates are included in the programme. Programs typically cover most government recommended vaccines or any vaccines administered by a recognised health professional. In many cases, there is supporting legislation that either lists vaccines by name (UK) or all vaccines related to the listed vaccine-preventable diseases (Quebec).

How does a claimant demonstrate that the vaccine caused an injury?

- Most no-fault programmes are designed for an administrative review of the injury, similar to other accident insurance or disability schemes, and do not require the claimant to seek legal representation or solicit expert medical review (beyond their attending physician's report). The assessment of claims is typically overseen by a medical director and follows a combination of an administrative review of eligibility criteria and a medical assessment performed by outside experts.

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Annex 1. Lessons from other Jurisdictions

Cont.

What types of medical and non-medical costs do most programmes cover?

- Most programmes are designed to cover *uninsured* medical costs, while others include special disability benefits, death benefits, economic damages (lost wages) and, in some cases, non-economic losses. In many jurisdictions, the settlement amount is calculated by agencies that typically deal with disability or accident claims. Compensation is frequently determined according to the rules governing accident or disability scales (as in Quebec) or determined by a life-planner (as in the United States). Lump sum settlements are issued in jurisdictions where there is a strong social safety net (UK and Norway)

How are most programmes funded?

- Because no-fault programmes for vaccine-related injuries tend to be fairly modest in scale, compared to other entitlement programmes, most are funded from general revenues. In the United States, the programme is funded by a special vaccine excise tax (paid by the purchasers) and in Sweden, Taiwan and Norway, a premium is paid by the vaccine manufacturer's themselves.

How predictable are the number of claims and settlements among the various no-fault compensation programmes and what kinds of programme components impact the overall payouts?

- Despite differences in approaches, administration, and eligibility criteria, data from four jurisdictions studied shows that the average number of claims and compensation amounts are relatively stable and predictable and represent both an affordable and reasonable expenditure as part of an overall national vaccination immunization programme. Still, the predicted number of settlements and the cost of any scheme does depend greatly on eligibility criteria, filing requirements, and the public's knowledge of the programme. The number of cases compensated *is* directly related to the eligibility requirements imposed by each system.

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BACKGROUND NOTE

DEPUTY MINISTER STEPHEN LUCAS CALL WITH CANADIAN MEDICAL PROTECTIVE SOCIETY (CMPA)

ISSUE:

The Canadian Medical Protective Society (CMPA) will meet with you to discuss the need for liability protection for doctors who administer COVID-19 vaccines.

BACKGROUND:

The CMPA is a not-for-profit organization that provides legal defense, liability protection, and risk management education for physicians in Canada. The CMPA defends its members sued in court for medical negligence causing injury. Physicians pay annual membership fees to the CMPA. Provincial governments reimburse a portion of those fees as part of negotiated contracts with provincial medical associations. [redacted]

As part of overall stakeholder outreach as part of implementation of the Vaccine Injury Compensation Program (VISP), PHAC officials met with the CMPA on February 5, 2021 to provide more information on the program. The meeting was positive and the CMPA expressed support for the program, stating that it was one more tool to help remove barriers with regards to the COVID-19 vaccine rollout. They did not explicitly raise the issue of liability protection during that conversation.

CONSIDERATIONS:

In its recent correspondence to you, the CMPA indicates that there is a need for liability protection related to COVID-19 vaccinations, and has associated this with the VISP currently being implemented by PHAC. They note that the US has provided liability protection to health workers administering COVID-19 vaccines. It is important to note, however that the US does not provide liability protection as part of its vaccine injury compensation regime. Rather, liability protection has been implemented through national emergency management legislation. A paper prepared by the Congressional Research Service is attached in Annex A, which provides an overview of the various measures the US has put in place at the federal level.

Similar to the US vaccine injury compensation program, the Canadian VISP program is not intended to protect doctors from medical malpractice lawsuits from individuals who are injured from the administration of a vaccine. The purpose of the VISP Program is to provide financial support to individuals with serious permanent injuries as a result of the administration of a Health Canada-authorized vaccine or immunoglobulin. It is a no-fault program intended to reinforce confidence in immunization programs. An important

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expected outcome of the program, however, is the diversion of claims from the court system by providing individuals with an alternative mechanism to seek compensation.

A key aspect of the Canadian VISP policy design is that an individual is not required to waive their right to pursue litigation if they receive support through the program. An individual would, however, be obligated to return any support received through the VISP program if there is a subsequent award through litigation.

[redacted]

Vaccine Injury Support Program

On December 10, 2020, the Prime Minister announced the creation of the pan-Canadian Vaccine Injury Support Program (VISP). The no-fault program will provide financial support to people in Canada in the rare event that they experience a serious and permanent injury after receiving a Health Canada authorized vaccine, administered in Canada. The program applies to all vaccines and immunoglobulins administered prophylactically, and will be retroactive to December 8, 2020. It fills a longstanding gap in Canada's overall vaccine strategy and bring us in line with the G7.

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The pan-Canadian VISP will build on the model in place in Quebec for over 30 years. All P/Ts have formally opted-in to the federal program, with the exception of Quebec, which will maintain its existing program.

As is the case for the Quebec model, financial support will include: injury indemnity, income replacement, death benefits, funeral expenses, and other expenses, such as uncovered medical and rehabilitation expenses.

PHAC is currently in the process of identifying a third party to administer the program. A Contribution Agreement (CA) was chosen as the funding mechanism, given the Health Portfolio's role in the promotion and regulation of vaccines. This mechanism provides a level of autonomy to the third-party in the administration of the program.

Four companies have submitted full proposals, following an open solicitation process which closed on February 24, 2021. A decision on the third-party is expected by mid-March.

Parliamentary Petition

There is currently a parliament petition that is calling for the federal government to:

1. Require the AGC to conduct a forensic examination of the CMPA for misappropriation of taxpayer dollars, ethics and conflicts of interest enabling negligence in patient care, profiteering as evident in their lavish work environment and breach of trust when denying culpability in patient related harm;

2. Defund the CMPA by eliminating the rebate program and return taxpayer dollars to taxpayer patients who experience medical errors; and

3. Repeal the Act of Parliament that incorporated the CMPA diminishing the hierarchical culture and restoring public trust.

The full petition is included in Annex B.

Prepared by: Centre for Immunization and Respiratory Infections Diseases [redacted]

February 27th, 2021

Contact: Stephen Bent, Director General, CIRID

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Annex A:

The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures
Congressional Research Service
Updated December 21, 2020

To encourage the expeditious development and deployment of medical countermeasures during a public health emergency, the Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (HHS) to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines. In a declaration effective February 4, 2020 (the HHS Declaration), the Secretary of HHS invoked the PREP Act and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures. Under the HHS Declaration, covered persons are generally immune from legal liability (i.e., they cannot be sued for money damages in court) for losses relating to the administration or use of covered countermeasures against COVID-19. The sole exception to PREP Act immunity is for death or serious physical injury caused by "willful misconduct." However, individuals who die or suffer serious injuries directly caused by the administration of covered countermeasures maybe eligible to receive compensation through the Countermeasures Injury Compensation Program.

Courts have characterized PREP Act immunity as "sweeping." It applies to all types of legal claims understate and federal law. For example, under state tort law, individuals who suffer injuries caused by the intentional or negligent acts or omissions of another person may generally sue that person to recover monetary compensation. Thus, in the health care context, if a health care provider negligently administers a drug or device that causes a foreseeable injury to a patient, the injured person may be able to sue the provider for compensation under state tort law.

Federal laws such as the PREP Act may preempt state tort laws—as well as other state and federal laws—in certain contexts. Preemptive federal legislation displaces state law to alter the usual liability rules or immunize certain individuals from liability. In the PREP Act, Congress made the judgment that, in the context of a public health emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered.

The Public Readiness and Emergency Preparedness Act

Scope of Immunity from Liability

For the PREP Act to apply, the Secretary of HHS (the Secretary) must determine that a disease or other threat to health constitutes a public health emergency, or that there is a credible risk of such an emergency. The Secretary shall consider the desirability of

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encouraging the design, development, testing, manufacture, and use of countermeasures in determining whether to issue a PREP Act declaration. (A PREP Act declaration is distinct from the Secretary's power to declare a public health emergency under Section 319 of the Public Health Service Act, which has a separate set of legal implications. The Secretary made a Section 319 declaration for COVID-19 on January 31, 2020.) The Secretary must publish the PREP Act declaration in the Federal Register and identify for each countermeasure the particular disease, time period, population, and geographical area that the declaration covers.

If within the scope of the declaration, the PREP Act immunizes a covered person from legal liability for all claims for loss relating to the administration or use of a covered countermeasure. The requirements for PREP Act immunity thus break down into four elements: (1) the individual or entity must be a "covered person"; (2) the legal claim must be for a "loss"; (3) the loss must have a "causal relationship" with the administration or use of a covered countermeasure; and (4) the medical product that caused the loss must be a "covered countermeasure."

First, the PREP Act defines a covered person to include (i) the United States; (ii) manufacturers and distributors of covered countermeasures; (iii) "program planners"; and (iv) "qualified persons" who prescribe, administer, or dispense covered countermeasures. Program planners include Indian Tribes, state governments, and local governments who supervise programs that dispense, distribute, or administer covered countermeasures, or provide policy guidance, facilities, and scientific advice on the administration or use of such countermeasures. Qualified persons include licensed health professionals and other individuals authorized to prescribe, administer, or dispense covered countermeasures understate law, as well as other categories of persons identified by the Secretary in a PREP Act declaration. Employees and agents of all these persons and entities are also covered persons.

Second, PREP Act immunity reaches "all claims for loss" under federal and state law. Loss is broadly defined to mean "any type of loss," including (i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of such injury, including medical monitoring costs; and (iv) loss of or damage to property, including business interruption loss. This language seemingly includes, at a minimum, most state law tort, medical malpractice, and wrongful death claims arising from the administration of covered countermeasures.

Third, the loss must have a causal relationship to the administration and use of a covered countermeasure. As with the other elements, the PREP Act's causation language sweeps broadly. PREP Act immunity applies to any claim for loss that has "a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use" of a covered countermeasure.

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Fourth, the medical product at issue must be a covered countermeasure. The PREP Act specifies four types of covered countermeasures: (i) a qualified "pandemic or epidemic product"; (ii) a "security countermeasure"; (iii) a drug, biological product, or device that the U.S. Food and Drug Administration(FDA) has authorized for emergency use; and (iv) a "respiratory protective device" that is approved by the National Institute for Occupational Safety and Health (NIOSH).

A pandemic or epidemic product includes any drug, biological product, or device developed "to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" or used "to limit the harm such pandemic or epidemic might otherwise cause." In addition, drugs, biological products, or devices used to treat the side effects of a pandemic or epidemic product, or to enhance their effects, may themselves be covered countermeasures. In either case, to be a covered countermeasure, the pandemic or epidemic product must be approved, licensed, or authorized for emergency use by FDA.

Security countermeasure refers to a drug, biological product, or device used "to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent" identified by the Secretary of Homeland Security as a material threat to national security.

The *emergency use* category of covered countermeasures includes drugs, biological products, and devices that FDA has authorized for use outside its ordinary regulatory processes via an Emergency Use Authorization (EUA). FDA has made wide use of its emergency authorities in response to the COVID-19pandemic, issuing EUAs for certain in vitro diagnostic products (i.e., tests for COVID-19), antibody tests, personal protective equipment (e.g., respirators and face shields), ventilators, therapeutic drugs, and—most recently—vaccines.

Section 6005 of the Families First Coronavirus Response Act and Section 3103 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) amended the PREP Act to add a fourth covered countermeasure category for certain respiratory protective devices (such as N95 respirators). To be covered by the PREP Act, the respiratory protective device must be: (i) approved by NIOSH under 42C.F.R. Part 84; and (ii) determined by the Secretary to be a priority for use during a public health emergency. FDA issued an EUA on March 2, 2020, for the use of NIOSH-approved filtering respirators intended for general use to protect health care personnel against COVID-19.

The "Willful Misconduct" Exception

If a claim is within the PREP Act's scope, a covered person is generally immune from legal liability. The "sole exception" to immunity is when a covered person proximately causes death or serious physical injury to another person through willful misconduct. A serious physical injury must be life threatening, permanently impair a body function, permanently damage a body structure, or require medical intervention to avoid such permanent impairment or damage. Willful misconduct requires that the covered person acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual

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justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

The process by which injured persons (or their representatives) may prove willful misconduct under the PREP Act is limited in several ways. Before filing a lawsuit claiming willful misconduct, injured persons must first seek compensation through the Countermeasures Injury Compensation Program (see below),and they cannot sue if they elect to receive that compensation. If they choose to file a lawsuit, injured persons may sue only in the U.S. District Court for the District of Columbia. Such lawsuits must meet heightened standards for pleading and discovery, and are subject to procedural provisions generally favorable to defendants. Injured persons must prove willful misconduct by clear and convincing evidence(a higher standard than in a typical civil case), and recovery for noneconomic damages such as pain and suffering is limited.

In addition to these procedural and substantive limitations, the PREP Act contains two statutory defenses to claims of willful misconduct. First, program planners and qualified persons cannot be found to have engaged in willful misconduct if they "acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure," and notify either the Secretary or a state or local health authority of the injury or death allegedly caused by the countermeasure within seven days. Second, countermeasure manufacturers and distributors may rely on regulatory compliance as a complete defense to a willful misconduct allegation. When the act or omission alleged to be willful misconduct is "subject to regulation" under the Public Health Service Act or the Federal Food, Drug, and Cosmetic Act (e.g., by FDA), an injured person cannot succeed on a willful misconduct claim unless the Secretary or the Attorney General has brought certain "enforcement actions" against the manufacturer or distributor that result in the imposition of particular penalties.

The Countermeasures Injury Compensation Program

An individual seriously injured or killed by the administration of a covered countermeasure, whether or not as a result of willful misconduct, may seek compensation through the Countermeasures Injury Compensation Program (CICP). CICP is a regulatory process administered by HHS's Health Resources and Services Administration. HHS regulations govern CICP's procedures and eligibility determinations. In general, eligible individuals (or their survivors) who suffer death or serious physical injury directly caused by the administration of a covered countermeasure may receive reimbursement for reasonable medical expenses, loss of employment income, and survivor benefits in the case of death. Serious physical injuries under CICP are generally limited to those that warrant hospitalization or led to a significant loss of function or disability. Congress funds CICP awards through emergency appropriations to the Covered Countermeasure Process Fund.

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Both the CARES Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA) appropriate funding that HHS may use for the Covered Countermeasure Process Fund. CPRS Appropriates $3.1 billion to the Secretary to respond to COVID-19, including the development and purchase of countermeasures and vaccines, while allowing these funds to "be transferred to, and merged with" the Covered Countermeasure Process Fund. Similarly, the CARES Act appropriates $27 billion to the Secretary for similar purposes, again providing that the Secretary may transfer these funds to the Covered Countermeasure Process Fund.

CICP is distinct from the National Vaccine Injury Compensation Program (VICP) which provides compensation for injuries caused by most vaccines routinely administered in the United States, such as childhood vaccines (e.g., MMR, polio, hepatitis A) and non pandemic seasonal influenza vaccines. By contrast, CICP only applies to countermeasures covered by a PREP Act declaration of a public health emergency, such as those issued for COVID-19, pandemic influenza (e.g., the 2009 H1N1 "swine flu"),and the Ebola virus. VICP is funded through an excise tax on licensed vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children or pregnant women.

While the PREP Act declaration for COVID-19 countermeasures remains in effect, persons seriously injured by the administration of a COVID-19 vaccine authorized by FDA through an EUA (such as the Pfizer-BioNTech mRNA vaccine or the Moderna vaccine) could seek compensation through CICP, not VICP. Generally speaking, compensation through CICP is somewhat more limited than VICP. For example, attorneys' fees and pain-and-suffering damages are not available through CICP, and the statute does not allow for judicial review of HHS's CICP-compensation determinations.

HHS's COVID-19 Declaration and Amendments

On March 10, 2020, the Secretary invoked the PREP Act and determined that COVID-19 constitutes a public health emergency. The HHS Declaration therefore authorizes PREP Act immunity for the "manufacture, testing, development, distribution, administration, and use" of covered countermeasures.(These activities, however, must either relate to present or future federal contracts, or be part of the public health response to COVID-19 authorized by an "authority having jurisdiction," such as federal, state, tribal, or local governments.) The immunity applies to all covered persons as defined in the PREP Act, including any person authorized by state and local public health agencies (or an EUA) to "prescribe, administer, deliver, distribute or dispense" covered countermeasures. Covered countermeasures include" any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19." The "administration" of a covered countermeasure includes "physical provision of the countermeasures" to patients, as well as "activities and decisions directly relating to . . . delivery, distribution and dispensing of" the countermeasures. The HHS Declaration provides PREP Act immunity "without

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geographic limitation" beginning on February 4,2020, and ending as late as October 1, 2025.

The HHS Declaration has been amended several times to broaden the scope of PREP Act immunity. First, on April 10, 2020, the Secretary amended the declaration to include NIOSH-approved respiratory protective devices as covered countermeasures, pursuant to the CARES Act's amendments to the PREP Act. Second, on June 4, 2020, the Secretary amended the declaration to clarify that drugs, biological products, and devices that "limit the harm COVID-19 might otherwise cause" are covered countermeasures, and that the HHS Declaration reaches "all qualified pandemic and epidemic products defined under the PREP Act."

A third amendment to the HHS Declaration (the Third Amendment), issued August 19, 2020, expanded the definitions of covered diseases and covered persons. First, HHS expanded the categories of disease representing a public health emergency to reach not just COVID-19, but also "other diseases, health conditions, or threats that may have been caused by COVID-19, SARS-CoV-2, or a virus mutating there from." In particular, such "other diseases" include diseases resulting from "the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases." The amendment thus declares that pediatric vaccines (if licensed by FDA and recommended by the CDC's Advisory Committee on Immunization Practices (ACIP)) are covered countermeasures.

Relying on the PREP Act's preemption provision, the Third Amendment adds a new category of "qualified persons" to authorize state-licensed pharmacists to administer ACIP-recommended vaccines to children aged three to eighteen, notwithstanding state laws to the contrary, if the pharmacists comply with certain federal requirements. Although pediatric vaccines are treated as covered countermeasures for preemptive purposes, the amendment nonetheless states that VICP will continue to apply to them "for the purposes of liability immunity and injury compensation," unless compensation is not available under that program.

The General Counsel of HHS has issued four advisory opinions on the PREP Act. Although these opinions are nonbinding and lack the force of law, they may inform the judicial interpretation of the PREP Act if courts find their reasoning persuasive. First, in an omnibus advisory opinion issued April 17, 2020(as revised May 19, 2020), the General Counsel summarized the elements for immunity under the PREP Act and set forth his view that immunity extends to (1) persons who "reasonably could have believed" that they were covered persons (even if they were not); and (2) products that a person "reasonably could have believed" were covered countermeasures (even if they were not). Second, in a May 19, 2020,advisory opinion, the General Counsel set forth his opinion that the PREP Act preempts any state or local requirement that effectively prohibits a pharmacist from ordering and administering an FDA-authorizedCOVID-19 diagnostic test. Third, on October 23, 2020, the General Counsel issued a third advisory opinion expressing his view that, with respect to the administration of pediatric vaccines by pharmacists

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authorized under the Third Amendment, the PREP Act preempts only more stringent state licensing laws, and that epinephrine, if used to treat an acute reaction to an ACIP-recommended vaccination, is a covered countermeasure. Fourth, and also on October 23, 2020, the General Counsel re-emphasized the breadth of PREP Act immunity, explaining that (1) private businesses may qualify as "program planners" (and thus covered persons) when performing certain functions, and (2) activities authorized by an "authority having jurisdiction" include uses of covered countermeasures recommended by applicable public-health guidance, such as CDC guidance.

Finally, on December 3, 2020, the Secretary issued a fourth amendment to the HHS Declaration. Among other things, the amendment states that the HHS Declaration "must be construed in accordance with" the HHS advisory opinions, which are expressly "incorporate[d]" into the Declaration. The fourth amendment makes several changes to expand the scope of PREP Act immunity, including "mak[ing] explicit" that the HHS Declaration (1) covers "all qualified pandemic and epidemic products" within the meaning of the statute; and (2) may apply to claims based on not administering a covered countermeasure, such as when the countermeasure is in short supply. The fourth amendment further creates a new category of "qualified persons" to cover health care providers using telehealth to order or administer covered countermeasures across state lines; adds a third covered means of distribution to extend liability protections to "additional private distribution channels"; and clarifies the licensing requirements for pharmacists to administer routine pediatric vaccinations under the Third Amendment, while expanding this category to expressly include FDA-authorized COVID-19 vaccines as well.

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Annex B – Parliamentary Petition

Petition to the House of Commons in Parliament assembled

Whereas:

The Canadian Medical Protective Association, founded in 1901, was incorporated by an Act of Parliament in 1913, and Canada remains after 120 years, worldwide, the only country with a medical protective association;

The Canadian Medical Protective Association states it is a not-for-profit association and yet has $5,400,000,000 in assets that increase annually;

The Canadian Medical Protective Association uses taxpayer dollars ($520,000,000+) that is transferred and increases annually in a rebate program to subsidize the association;

The Canadian Medical Protective Association does not have public oversight, instead is governed by by-laws developed by membership and is therefore self-regulated/self-policed; and

The Canadian Medical Protective Association hires top tier lawyers who use scorched earth tactics to defend doctors accused of medical errors and these court cases can last from five to eight years, with only two percent of cases settled in favour of the patient/family.

We, the undersigned, citizens of Canada, call upon the House of Commons in Parliament assembled to:

1. Require the Attorney General of Canada to conduct a forensic examination of the Canadian Medical Protective Association program for improprieties, including misappropriation of taxpayer dollars that are being used for actions outside the realm of reasonable behaviors, ethics and conflicts of interest enabling negligence in patient care, profiteering as evident in their lavish work environment and breach of trust when denying culpability in patient related harm;

2. Defund the Canadian Medical Protective Association by eliminating the rebate program and return taxpayer dollars to taxpayer patients who experience medical errors; and

3. Repeal the Act of Parliament that incorporated the Canadian Medical Protective Association diminishing the hierarchical culture and restoring public trust.

Richard Cannings
South Okanagan—West Kootenay
New Democratic Party Caucus
British Columbia

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Canada

SECRET

IMPLEMENTATION UPDATE: PAN-CANADIAN NO-FAULT VACCINE INJURY SUPPORT PROGRAM

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Purpose

- Provide an update on implementation of the pan-Canadian no-fault Vaccine Injury Support Program (VISP).

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Background

- The Prime Minister announced the creation of the VISP following the First Ministers' Meeting on December 10, 2020

- The pan-Canadian VISP will build on the model in place in Québec for over 30 years.

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Four areas of work to implement the program…

FPT Engagement

- Engagement to date
- Status of PT participation

Program Design

- Engagement, intelligence gathering, and analysis
- Considerations
- Securing program and funding authorities
- Timelines

Third Party Selection

- Proposed Solicitation approach
- Identified potential 3rd parties
- Timelines

Communications

- Announcements
- Web presence
- Public Reception
- Proposed increased web presence

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FPT Engagement

- Presented at key FPT tables, including Special Advisory Committee (December 3, 2020), Conference of Deputy Ministers of Health (December 11, 2020), and Health Ministers' Meeting (December 17, 2020).

- Initial feedback from PTs has been fully supportive

- Request for formal "Opt-in / Opt-out" confirmation sent to PTs, with a return date of January 15, 2021. Responses to date (Jan 18):
  - Total number of PTs participating in pan-Canadian VISP: 8 (MB, NWT, NU, NS, BC, YK, NFLD, ON)
  - Total number of PTs opting out to establish/maintain their own equivalent program: 1 Qc

- Quebec signalled early on that it intends to maintain its current program with access to federal funding.

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Program Design

- [redacted] However, some aspects require further development:
- The intent is that the pan-Canadian VISP will align with Quebec's existing program as much as possible, in order to ensure equivalent programming across Canada.
- However, not all elements will be replicable at the national level. For example, QC uses their provincial automobile insurance program to calculate and administer payments to successful claimants.
- Discussions with officials from the *Ministère de la santé et des services sociaux du Québec* are underway to fully understand their program parameters (see annex), including engagement with the *Société de l'assurance automobile* to better understand QC's payment schedule/formula.
- Consultations have also taken place with federal departments to assess various approaches taken for other compensation programs:
  - VAC (compensation for service-related illness or injury); Public Safety (Memorial Grant Program for first responders), Health Canada (Thalidomide Survivors Support Program) and Indigenous Services Canada (Common Experience and Independent Assessment programs for residential school survivors).

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Program and spending authorities

[redacted]

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Third Party Administrator

- Solicitation approach based on balancing the need to rapidly determine if there are any Canadian organizations who are interested and have the ability/capacity to deliver this program, while ensuring the selection is fair and transparent.
- An open solicitation, along with targeted outreach to identified organizations (see appendix) will be launched in late early February.
- Expressions of interest will initially be sought, followed by full Invitations to Submit Funding Request (ISFR). Eligibility criteria will be specific. As such, we do not expect a large number of applicants.
- Eligibility criteria will include:
  - Experience in health claim adjudication (including an appeal mechanism)
  - Ability to deliver the program at a national level in both official languages
  - Experience in the management of personal information
- The Contribution Agreement with selected Third Party Administrator would be for 5 years followed by review.
- PHAC will administer the program, if there is no suitable third party identified.

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Communications

- VISP was announced by the PM on December 10, 2020 following the First Ministers' Meeting. A news release is accessible online.
- High level information regarding the VISP was added to the Vaccine safety page on the PHAC website on December 23, 2020.
- There is increasing interest by stakeholders and Canadians to have more information on the program design and eligibility.
- PHAC will develop a dedicated webpage for VISP. Approval will be sought to disclose additional program details such as:
  - Program design elements, including the solicitation for a 3rd party to delivery the program.
  - Further clarification on eligibility
  - The eligibility date of December 8, 2020 This will help in managing enquiries.
  - Deadline to apply for benefits (i.e. 3 years from vaccination with a HC-approved product administered in Canada.
  - Anticipated program launch date of June 2021.

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Next Steps/Key Dates

- Continue engagement with PTs (ongoing)
- Continue engagement with various stakeholders and experts to inform program parameters (ongoing)
- [redacted]
- Launch third party solicitation process (Feb 2021)
- [redacted]
- Finalize contribution agreements (May 2021)
- Program launch expected by June 2021, with third party accepting claims for immunizations received as of December 8, 2020

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Annexes

ATIA - 20(1)(b) ATIA - 20(1)(c)

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List of potential third party administrators*

Claims Administrators

[redacted]

Insurance Providers

[redacted]

Consulting/pension service provider

- Raymond Chabot Grant Thornton Consulting Inc.

[redacted]

Others

[redacted]

Third Parties Currently Administering Federal Programs

- Raymond Chabot Grant Thornton Consulting Inc. Public Safety Memorial Program
- Epiq Class Action Services Canada - Health Canada Thalidomide Survivors Support Program
- Epiq Class Action Services Canada - Indigenous Services Canada Independent Assessment Program
- Medavie Blue Cross - Administer various government-sponsored health programs on behalf of provincial and federal governments, including Veterans Affairs Canada and Immigration, Refugees and Citizenship Canada

**List compiled from Thalidomide process, engagement with OGDs, and others*

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Recap – VISP Drivers

Long-standing gap	• Establishing a national compensation program would leave a legacy of a strengthened immunization system in Canada.
Fairness and equity	• Currently, we indemnify pandemic vaccine manufacturers, but not injured Canadians. • Without a national program, only Quebec residents have access to a no-fault compensation program creating inequity across jurisdictions.
Securing supply	• As the only G-7 country without a national vaccine injury compensation program, Canada could be disadvantaged in vaccine procurement if some suppliers require this as a condition for accessing their product. • Removes barriers to market entry for smaller manufacturers.
Leadership and responsibility	• Demonstrates that Canada, like other countries, recognizes that in the rare instances of serious harm due to vaccination, it is right that individuals receive compensation.

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Key Quebec Program Information

- Since its creation by legislation in 1988, 284 cases (approx. 7 annually) have been filed with Quebec's no-fault vaccine injury compensation program; of these cases, 53 claims (close to 2 annually) were accepted and another 44 claims were not pursued.
- Over 32 years, Quebec's program has issued $6.5 million (approx. $250K annually) to successful claimants. Compensation has averaged $123K per successful claim.
- Under Quebec's model, applications must be filed within 3 years of when the vaccination occurred in Quebec. Quebec's program convenes an expert evaluation committee to review the cases and recommend compensation. The Minister of Health decides whether to award compensation. If the decision is in favour of the applicant, the government has a third-party agreement with Société de l'assurance automobile du Québec (which calculates and pays the compensation).
- Claims are heard by a three-person medical expert evaluation committee and decided by a 2/3 majority opinion. One member is nominated by the claimant, the other by the government, and the chair of the committee is chosen by the other two committee members.
- Unsuccessful claimants may file an appeal to the Administrative Tribunal of Quebec